

California Department of Health Services

Pandemic Influenza Preparedness and Response Plan



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An annex to the CDHS Public Health
Emergency Response Plan and Procedures

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1.0 Introduction

1.1 Pandemic Influenza Background

Influenza, also known as the flu, is a disease that attacks the respiratory tract (nose, throat, and lungs) in humans. Different from a viral “cold,” influenza usually comes on suddenly and may include fever, headache, tiredness (which may be extreme), dry cough, sore throat, nasal congestion, and body aches. Seasonal influenza is a yearly occurrence that causes minor economic impact and kills primarily persons aged 65 and older. It also provides immunity to those who are exposed, but do not succumb, to the virus.

World-wide pandemics of influenza occur when a novel (new or different) virus emerges to which the population has little immunity. During the 20th century there were three such pandemics, the most notable of which was the 1918 Spanish influenza responsible for 20 million deaths throughout the world. Public health experts are currently concerned about the risk of another pandemic, arising from the current epidemic of avian influenza that has been affecting domestic and wild birds in Asia and spreading rapidly to other parts of the world. When such strains of avian influenza interact with the common strains of human influenza, a mutation can occur that leads to a virus capable of human-to-human transmission, initiating a pandemic strain of influenza. Depending on the infectivity of such a virus and its disease-causing potential, experts estimate that as many as 35 percent of the population will become ill and there could be more than 35,000 deaths in California due to pandemic influenza. This level of disease activity would disrupt all aspects of society and severely affect the economy.

The impact of an actual pandemic cannot be predicted precisely, as it will depend on the virulence of the virus, how rapidly it spreads, the availability of vaccines and antivirals, and the effectiveness of medical and non-medical containment measures.

1.2 Pandemic Influenza Preparedness and Response Plan Overview

This plan is an annex to the California Department of Health Services (CDHS) *Public Health Emergency Response Plan and Procedures*. CDHS will carry out the response activities described in this plan in collaboration with the Emergency Medical Services Authority (EMSA), the California Health and Human Services Agency (CHHSA), the Governor’s Office of Emergency Services (OES), other state agencies, and local health departments (LHDs). This CDHS Pandemic Influenza Preparedness and Response Plan outlines key assumptions for pandemic planning and response, summarizes relevant legal and statutory authorities, explains the CDHS emergency management organization and defines a concept of operations for pandemic influenza response. Appendices describe essential functions for conducting surveillance, case investigation, and treatment; preventing spread of the disease in the community; maintaining essential services; and other actions prior to, during, and after a pandemic. Although the term “pandemic” can refer to any disease outbreak that becomes a worldwide epidemic, this plan uses the terms “pandemic influenza” and “pandemic” interchangeably.

1.3 World Health Organization (WHO) Pandemic Phases

This plan rests on a conceptual framework of public health functions (surveillance, investigation, intervention), coupled to WHO’s pandemic phases described below.

Interpandemic period

WHO Phase 1. No new influenza virus subtypes have been detected in humans. An influenza virus subtype that has caused human infection or disease may or may not be present in animals. If present in animals, the risk of human infection or disease is considered to be low.

WHO Phase 2.¹ No new influenza virus subtypes have been detected in humans. However, a circulating animal influenza virus subtype poses a substantial risk of human disease.

Pandemic alert period

WHO Phase 3. Human infection(s) with a new subtype, but no human-to-human spread, or rare instances of infectious spread to a close contact.

Examples:

- one or more unlinked human cases with a clear history of exposure to an animal or other non-human source (with laboratory confirmation in a WHO-designated reference laboratory);
- rare instances of spread from a case to close household or unprotected health-care contacts without evidence of sustained human-to-human transmission;
- one or more small independent clusters of human cases (such as family members) who may have acquired infection from a common source or the environment, but for whom human-to-human transmission cannot be excluded; and/or
- persons whose source of exposure cannot be determined, but who are not associated with clusters or outbreaks of human cases.

WHO Phase 4. Small cluster(s) with limited human-to-human transmission but spread is highly localized, suggesting that the virus is not well adapted to humans.

Examples:

- one or more clusters involving a small number of human cases, e.g., a cluster of less than 25 cases lasting less than two weeks; and/or

¹ The distinction between **Phases 1** and **2** is based on the risk of human infection or disease resulting from circulating strains in animals. The distinction is based on various factors and their relative importance according to current scientific knowledge. Factors may include pathogenicity in animals and humans, occurrence in domesticated animals and livestock, (as opposed to only in wildlife), whether the virus is enzootic or epizootic, whether the virus is geographically localized or widespread, and/or other scientific parameters.

- appearance of a small number of human cases in one or several geographically linked areas without a clear history of a non-human source of exposure, for which the most likely explanation is considered to be human-to-human transmission.

WHO Phase 5. Larger cluster(s), but human-to-human spread is still localized, suggesting that the virus is becoming increasingly better adapted to humans, but may not yet be fully transmissible (substantial pandemic risk).

Examples:

- ongoing cluster-related transmission, but total number of cases is not rapidly increasing, e.g., a cluster of 25–50 cases lasting from two to four weeks;
- ongoing transmission, but cases appear to be localized (remote village, university, military base, island);
- in a community known to have a cluster, appearance of a small number of cases whose source of exposure is not readily apparent (e.g., beginning of more extensive spread); and/or
- appearance of clusters caused by the same or closely related virus strains in one or more geographic areas without rapidly increasing case numbers.

Pandemic period

WHO Phase 6. Increased and sustained transmission in the general population.

Postpandemic Period

Although not part of the WHO Phases for tracking the emergence of a pandemic, mitigation and recovery should be a part of every emergency response plan. Mitigation and recovery actions should be focused on continuing public health actions including communication with the public on issues such as when public gatherings can resume, and continued monitoring of possible outbreaks of infection.

2.0 Goal of the CDHS Pandemic Influenza Response Plan

Consistent with CDHS' mission "to protect and improve the health of all Californians," this plan provides a framework for CDHS pandemic influenza preparedness and response activities. The goal of these activities is to reduce the morbidity, mortality, and social and economic disruption caused by pandemic influenza. The plan is consistent with the November 2005 U.S. Department of Health and Human Services' Pandemic Influenza Plan.

The CDHS plan outlines the roles and strategies of CDHS in coordinating the public health response to a pandemic with LHDs, the healthcare community, the federal government, and other key partners. The appendices provide a framework for preparedness activities of these parties.

3.0 Assumptions for CDHS Pandemic Influenza Planning and Response

The key assumptions and limitations guiding CDHS pandemic influenza planning and response activities are listed below.

- A pandemic is a public health emergency that rapidly takes on significant political, social, and economic dimensions. A broad range of private sector partners and government entities in addition to public health should be engaged in pandemic preparedness planning. A pandemic is likely to affect everyone in California, from teachers and grocery store owners to farm workers and high-tech researchers. No amount of planning will allow response to a major pandemic to be “business as usual.”
- The course of pandemic influenza will be governed by factors that cannot be known in advance. Properties of the novel virus, including its pathogenicity, principal mode of transmission, timing and duration of viral shedding, and attack rate in different risk groups may differ from those of interpandemic influenza strains.
- The first human cases caused by a novel influenza virus will likely occur in other countries and will be detected by the global surveillance network.
- Experts anticipate an influenza pandemic could last from 18 months to several years with at least two peak waves of activity.
- Activities identified in any given pandemic phase are not necessarily assumed to be completed during that phase; activities started in one phase may continue into subsequent phases.
- Decisions about non-medical containment measures will be made in an atmosphere of considerable scientific uncertainty. Containment measures must be adapted to the epidemiological context of each pandemic influenza phase of the pandemic.
- Non-medical containment measures will be the principal means of disease control until adequate supplies of vaccine and/or antiviral medications are available.
- Vaccination and antiviral treatment are anticipated to be the most effective medical strategies for reducing pandemic influenza morbidity and mortality. However, effective vaccines or antiviral medications may be non-existent or in limited supply. CDHS will promote and coordinate use of vaccines and/or antivirals based on their availability and the best scientific evidence at the time.
- California’s standard operating procedure is for all levels of governance to coordinate emergency response activities through the Standardized Emergency Management System (SEMS). CDHS, working with OES, will continually strive to assure compliance with SEMS and the National Incident Management System (NIMS).
- CDHS may take actions described in this plan and/or activate its emergency management organization without a declaration of local, state, or health emergency. Depending on the situation, CDHS may activate all or portions of the plan.

- California's public health system relies on LHDs with authority and responsibility for public health preparedness and response at the local level. CDHS provides leadership, support, and coordination of this effort, including during a multi-jurisdictional emergency. Although pandemic influenza may affect multiple jurisdictions simultaneously, all jurisdictional responsibilities are maintained. CDHS will provide additional support to leadership at the local level, without usurping the authority of LHDs.
- CDC will characterize viral isolates, provide technical assistance, and quickly inform state health departments as new information becomes available. CDHS will activate its risk communication strategies and quickly disseminate public advisories and alerts based on CDC and other credible sources of information.
- CDHS may modify and further define the federal guidance, as necessary for allocation of vaccines and antivirals to California's LHDs. CDHS' Emergency Pharmaceutical Services Unit (EPSU) will be responsible for procuring and distributing vaccines and antiviral drugs that are made available to the State.
- Planning for continuity of government (for state and local governments) and continuity of operations (for the private sector) is an essential component of pandemic influenza preparedness. This plan, which does not directly address continuity of operations/continuity of government, assumes that this planning will occur in the public and private sector.
- Communication is a critical aspect of all emergency planning and response. Priority must be given to ensuring timeliness and accuracy of communication by all programs involved in planning for and responding to pandemic influenza and all other public health emergencies. Procedures and protocols for incorporating regular communication actions will be included into each phase of pandemic influenza planning and response to facilitate sharing of information and messages within CDHS as well as with other response partners at the state and local level and the public.

4.0 Authorities and References

- California Emergency Service Act (Government Code (GC), Title 2, Division, Chapter 7, Section 8550 *et seq.*): Confers upon the Governor and chief executives of political subdivisions of the state emergency powers to provide for state assistance in organization and maintenance of emergency programs; establishes OES; assigns functions to state agencies to be performed during an emergency and provides for coordination and direction of emergency actions of those agencies; and, establishes mutual aid procedures. Authority for the creation of standby orders, crucial for preparedness, exists in GC section 8567. Authority to suspend statutes and agency rules exists in GC section 8671.
- California Health and Safety (H&S) Code Sections Pertaining to State Authorities:
 - Sections 100170-100180: Establishes authority of CDHS to enforce the H&S Code regulations to address threats to the public health.

- Sections 120125-120140: Establishes authority of CDHS to investigate and control communicable disease within the state.
 - Sections 120145-120150: Establishes authority of CDHS to take actions related to persons, animals, or property to control threats to public health, including quarantine, isolation, inspection, disinfection, and destruction of property.
- California H&S Code Sections Pertaining to Local Authorities:
 - Sections 101000, 101025, 101030: Establishes authority of county health officers to preserve and protect the public health by enforcing county orders, ordinances, and statutes pertaining to public health.
 - Sections 101375, 101400, 101405, 101415, 101450, 101460, and 101470: Establishes authority of cities to consent or contract with the county to provide performance of public health functions and statute enforcement. In absence of consents or contracts with the county, authorizes cities to appoint a health officer to enforce and observe all orders, ordinances, quarantines, regulations, and statutes relating to public health.
 - Sections 101040, 101475: Authorizes county and city health officers to take preventive measures during emergency.
 - Section 120175: Authorizes the local health officer to take measures necessary to control the spread of communicable diseases.
- Executive Order No. W-9-91: Mandates that each state agency and department (e.g., CDHS) is responsible to prepare for and respond to emergencies. It mandates emergency preparedness and response assignments for all state agencies and departments under the coordination of OES.
- Administrative Order No. 79-22 (12/10/02): Details the emergency preparedness and response functions of each department (e.g., CDHS). This Administrative Order guides OES and all departments in coordinating priority tasks and programs related to emergency preparedness, response, and recovery in accordance with the OES *State Emergency Plan*.
- California Department of Health Services, *Emergency Response Plan and Procedures*, November 2005
- Emergency Medical Services Authority, *Disaster Medical Response Plan*, July 1992.
- Memorandum of Understanding, Department of Health Services and Emergency Medical Services Authority, July 1988: Details the relationship between CDHS and EMSA in planning for and responding to a catastrophic disaster and describes the specific responsibilities of each department.
- Office of Emergency Services, *State Emergency Plan*, May 1998: Defines the emergency management system used for all emergencies in California. The plan describes the state government's response to disasters, including the response of all levels of government and certain private sector organizations to all natural and

human-made emergencies that threaten life, property, and the resources of California. It focuses on the basic requirements for disaster management and coordination under the SEMS. It is intended to be used in conjunction with city, county, operational areas, and state agency plans and associated standard operating procedures. The State Emergency Plan recognizes and designates CDHS as the lead State department for public health responses.

- Federal Emergency Management Agency, *National Response Plan*, December 2004: An all-discipline, all-hazards plan that provides a single, comprehensive framework for the management of domestic incidents. It provides the structure and the mechanisms for coordinating delivery of federal assistance and resources to augment efforts of state, local, and tribal governments overwhelmed by a major disaster or emergency. It includes 32 signatory partners, including numerous federal departments, the American Red Cross, the National Voluntary Organizations Active in Disaster and other entities. It supports implementation of the Robert T. Stafford Disaster Relief and Emergency Assistance Act and for exercising direct Federal authorities and responsibilities. For events that rise to the level of an Incident of National Significance, it provides operational and/or resource coordination for Federal support to on-scene incident command structures.
- Regional Medical/Health Coordinator Emergency Plans: These plans are prepared by each Regional Medical/Health Coordinator to describe their local disaster response roles.

5.0 Emergency Management Organization

The CDHS Pandemic Influenza Preparedness and Response Plan is an emergency-specific annex to the CDHS *Public Health Emergency Response Plan and Procedures*. The CDHS plan describes the relationship of CDHS to the state emergency response structure and the roles and responsibilities of CDHS Executive Staff, and the various divisions, branches, and sections of the department. This section describes the emergency management structure that CDHS will implement for pandemic influenza preparedness and response.

CDHS is the lead state department for the State's pandemic influenza response. CDHS' response to a pandemic will comply with SEMS/NIMS. CDHS will work closely with EMSA in coordinating the medical response. CDHS has primary responsibility for activating the pandemic influenza response at the level appropriate to the specific phase of a pandemic. Within CDHS, the structure of the response organization will include a Disaster Policy Council, a Joint Emergency Operations Center (JEOC), and various program coordination centers. The relationships of various groups are described below.

- **CDHS Directorate:** The Director of CDHS and the State Public Health Officer are responsible for the CDHS pandemic response. Specifically, the Director and State Public Health Officer will:
 - in coordination with the Emergency Preparedness Office (EPO), activate the CDHS emergency management organization as appropriate;

- activate the CDHS Disaster Policy Council (DPC)¹ to make high-level policy decisions and ensure that all CDHS organizational units implement these decisions;
 - provide policy direction to the emergency management groups and other state and local agencies detailed in this plan;
 - ensure that all necessary CDHS resources are directed to respond to the emergency; and
 - ensure that continuity of CDHS management and operations is maintained through a clear command authority.
- The **Disaster Policy Council (DPC)** is activated by, and works under, the Director of CDHS and the director of EMSA and is composed of the Directors of CDHS and EMSA, the State Public Health Officer, and other CDHS executive staff, to recommend high-level policy decisions that govern the Department's response and recovery activities. The DPC acts as an ad hoc advisory body to advise the Director on issues related to CDHS' disaster response.
- The **CDHS Joint Advisory Committee (JAC) on Public Health Preparedness** will serve as the coordinating committee on pandemic influenza issues. The JAC will advise CDHS on the formulation of policy and multi-agency preparedness and planning. This group will advise on preparedness activities and efforts as outlined in the plan. At the discretion of the Director, members of the JAC may also function as the Multi-Agency Coordination (MAC) group during an emergency. CDHS may convene technical consultants and/or other ad hoc advisory groups as needed to address specific issues.
- A **Multi-Agency Coordinating (MAC) Group** is established when multiple disciplinary or jurisdictional areas are involved and incident management and policy coordination is required. The MAC Group will be composed of the Director, the State Public Health Officer, members of the JAC and other principals (or their designees) from organizations and agencies with direct incident management responsibilities or significant incident management support or resource responsibilities. The MAC Group will function in conjunction with the JEOC. The MAC Group will:
 - ensure that each agency involved with incident management activities is providing appropriate situational awareness and resource status information;
 - establish priorities between incidents, acquiring and allocating resources in concert with those priorities, and identifying future resources requirements;
 - coordinate and resolve policy issues arising from the incidents; and
 - provide strategic coordination as required.

¹ CDHS Public Health Emergency Response Plan and Procedures

- The **CDHS-EMSA Joint Emergency Operation Center (JEOC)** coordinates state-level medical and health response and resources by acquiring public health and medical personnel, medical supplies, pharmaceuticals and equipment upon the request of an affected local area or region, coordinates resource acquisition and support for CDHS field emergency response activities. The JEOC coordinates with OES at the State Operations Center (SOC) or Regional Emergency Operations Centers (REOCs), as appropriate. Additionally, the JEOC ensures information flow to CDHS division coordination centers or branches and other state agencies, and ensures coordination and information flow with federal agencies, LHDs, tribal governments, healthcare organizations, and other providers of medical care, facilities, and supplies. The JEOC includes representation from CDHS and EMSA programs involved in the response. However, program activities occur within the responsible divisions, branches, sections, or units. For programs located at the Richmond Campus, the Richmond Campus Coordination Center (RCC) serves as the physical location of the program's response. This includes the Division of Communicable Disease Control (DCDC) as the lead CDHS Program on pandemic influenza planning and response (see DCDC below). An abbreviated organization chart for the JEOC during a pandemic influenza response is shown in Figure 6.
- The **Risk Communication Team** consists of the Office of Public Affairs (OPA), the EPO Risk Communication Section and representation from DCDC. This team works collaboratively to provide all aspects of needed public information and support to LHDs. During activation, OPA maintains its lead role in providing information to CDHS Executive Staff, CHHSA, the Governor's Office, Legislature and the news media. The Risk Communication Team coordinates the CDHS overall response with OPA, EPO, DCDC communication liaison, LHDs, OES/Joint Information Center, and EPSU. The Risk Communication Team also provides lead response on the CDHS EPO website, and issues appropriate California Health Alert Network (CAHAN) alerts, fact sheets, translations of materials, Hotline and support materials needed as part of an overall public information campaign.
- The **Division of Communicable Disease Control (DCDC)** is the lead CDHS program during a pandemic influenza. The DCDC Division Chief will:
 - manage or designate responsibility to DCDC staff to assist in the development of an Action Plan in coordination with the JEOC and involved programs, such as Licensing & Certification Division (L&C) and EPO, and to ensure its implementation by DCDC programs;
 - provide DCDC liaisons to participate in the JEOC and ensure coordination of program activities; and
 - ensure activation of all elements of the Pandemic Influenza Preparedness and Response Plan that are within the scope of DCDC, including the Richmond Campus Coordination Center, and provides overall coordination among the programs comprising the DCDC response.
- The **DCDC Pandemic Influenza Work Group (PIWG)** is composed of the Pandemic Influenza Coordinator, the Chiefs of Immunization Branch (IZB), Viral & Rickettsial Disease Lab (VRDL), Infectious Diseases Branch (IDB), and others, and provides

expert technical consultation and advice to DCDC on pandemic influenza containment issues.

- The **DCDC Field-based Pandemic Influenza Technical Specialist and/or Assessment Teams** (comprising two Field-Based Pandemic Influenza Technical Specialists, typically a physician and a nurse or epidemiologist) may be deployed to provide technical consultation on pandemic influenza control tactics to Operational Area (OA)/Regional Emergency Operations Center (OA/REOC) planning-intelligence branch(es) or directly to the local health officer (LHO). Field Technical Specialists and Liaisons remain under the supervision of the DCDC Coordination Center but do not supersede OA/REOC management.
- The **CDHS EPO Emergency Pharmaceutical Services Unit (EPSU)** will be responsible for procuring and distributing vaccines and antiviral drugs that are made available to the State and as directed by the DPC and/or MAC Group, if established.
- The **CDHS Food and Drug and Radiation Safety Section** will assist with the holding and control of necessary drugs and medical supply stocks intended for wholesale distribution, if the appropriate Governor's Standby Order has been implemented.
- The **CDHS Licensing and Certification Division (L&C)** is responsible for regulating and promoting the highest quality of medical care in community settings and facilities. Healthcare surge capacity will be a key element of the response to pandemic influenza. L&C plays a key role in response activities and in the field working with licensed facilities on beds, staffing and medical equipment needs to respond to pandemic influenza patients.

California Department of Health Services

CDHS Organization Chart for Pandemic Influenza

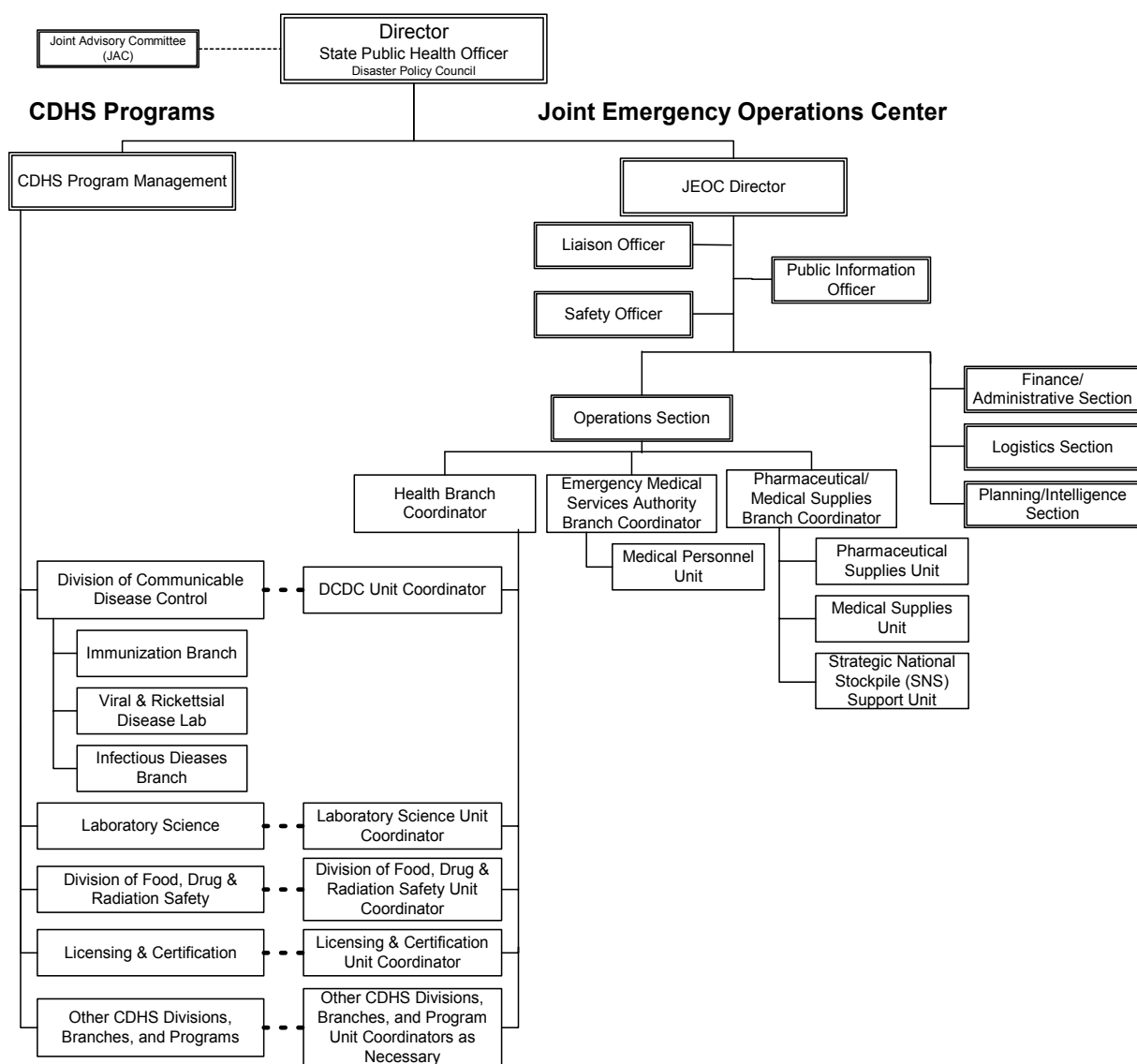


Figure 5: The CDHS Organizational Chart for Pandemic Influenza.

Solid lines denote official relationships and information flow.
Dotted lines denote unofficial information channels and notification.

6.0 Concept of Operations

6.1 Synopsis of Operational Priorities

Operational priorities for CDHS in response to a potential pandemic are to:

- ensure rapid and early detection of a novel virus;
- confirm detection of a novel virus by laboratory identification;
- identify the exposure source and the population at risk;
- control and contain the spread of influenza through medical and non-medical containment strategies including isolation, quarantine, infection control, antiviral treatment and prophylaxis, and, if available, vaccination;
- manage and disseminate accurate information for scientific, resource, and policy decisions in public health and healthcare delivery settings;
- disseminate information to enlist public support and enable personal, community, and business-based preparedness and response;
- track and respond to secondary pandemic influenza waves;
- coordinate state and federal activities with local public health partners; and
- coordinate the medical and healthcare response.

Staff in all CDHS divisions, branches, and programs may be mobilized during an emergency to fill positions and perform duties outside their normal roles and work hours.

These concepts and activities are further described in the appendices and attachments to the plan.

6.2 Operational Priorities by Pandemic Phase

WHO will designate the global pandemic phase, using the phases outlined in the Introduction of this plan. CDC, in coordination with WHO, will designate the U.S. pandemic phase. CDHS will adopt and function under the U.S. phase. The global and U.S. phases may differ. Due to the nature and impact of a pandemic, different operational priorities will pertain in different pandemic phases. These are summarized in Table 6.

Table 6: Pandemic Phase Operational Priorities

Pandemic Phases	Operational Priorities
Interpandemic period <i>Phase 1</i> <i>Phase 2</i>	Strengthen pandemic influenza preparedness at the state and local levels. Minimize the risk of transmission to humans; coordinate with CDFA regarding infected bird populations and CDFA's possible request for state of emergency proclamation; ensure rapid detection and reporting of the first occurrence of the novel virus in humans.
Pandemic alert period <i>Phase 3</i> <i>Phase 4</i> <i>Phase 5</i>	Ensure rapid characterization of the new virus subtype and early detection, notification and response to additional cases. Contain the new virus within limited foci or delay spread to gain time to implement preparedness measures, including vaccine development. Maximize efforts to contain or delay spread, to possibly avert a pandemic, and to gain time to implement pandemic response measures.
Pandemic period <i>Phase 6</i>	Minimize the impact of the pandemic, while striving to maintain routine provision of public health and healthcare delivery.
Postpandemic Period <i>Mitigation and Recovery</i>	Continue public health actions, evaluations and research, public communications, mental health activities, surveillance, and preparations for reoccurring or additional outbreaks

6.3 Planning and Preparedness

Prior to sustained human-to-human transmission of a novel pandemic influenza strain, CDHS is responsible for ongoing preparedness activities, including:

- convening advisory groups to advise CDHS on the Pandemic Influenza Preparedness and Response Plan and issues related to its implementation;
- identifying public and private sector partners needed for effective planning and response;
- developing the pandemic influenza preparedness plan: conducting surveillance, laboratory testing, case management and treatment; obtaining and distributing vaccine and antivirals; preventing the spread of disease in the community; conducting healthcare facilities planning; and communicating to the public;

- integrating pandemic influenza planning with other planning activities conducted under CDC and Health Resources and Services Administration (HRSA) bioterrorism preparedness cooperative agreements;
- coordinating with LHDs to ensure development of local plans as called for by the state plan and providing planning resources, such as templates and training;
- developing data management systems needed to implement components of the plan;
- identifying and training CDHS staff to manage and facilitate response during a long-term emergency;
- assisting LHDs in exercising plans and coordinating with adjoining jurisdictions;
- enhancing LHD's influenza-like illness surveillance efforts through training and laboratory support;
- developing guidelines for healthcare facilities and healthcare delivery organizations related to planning, preparedness, and response;
- specifying the activation thresholds for the JEOC;
- activating and maintaining the JEOC;
- evaluating LHD pandemic influenza plans; and
- providing guidance to the private sector regarding continuity of operations planning.

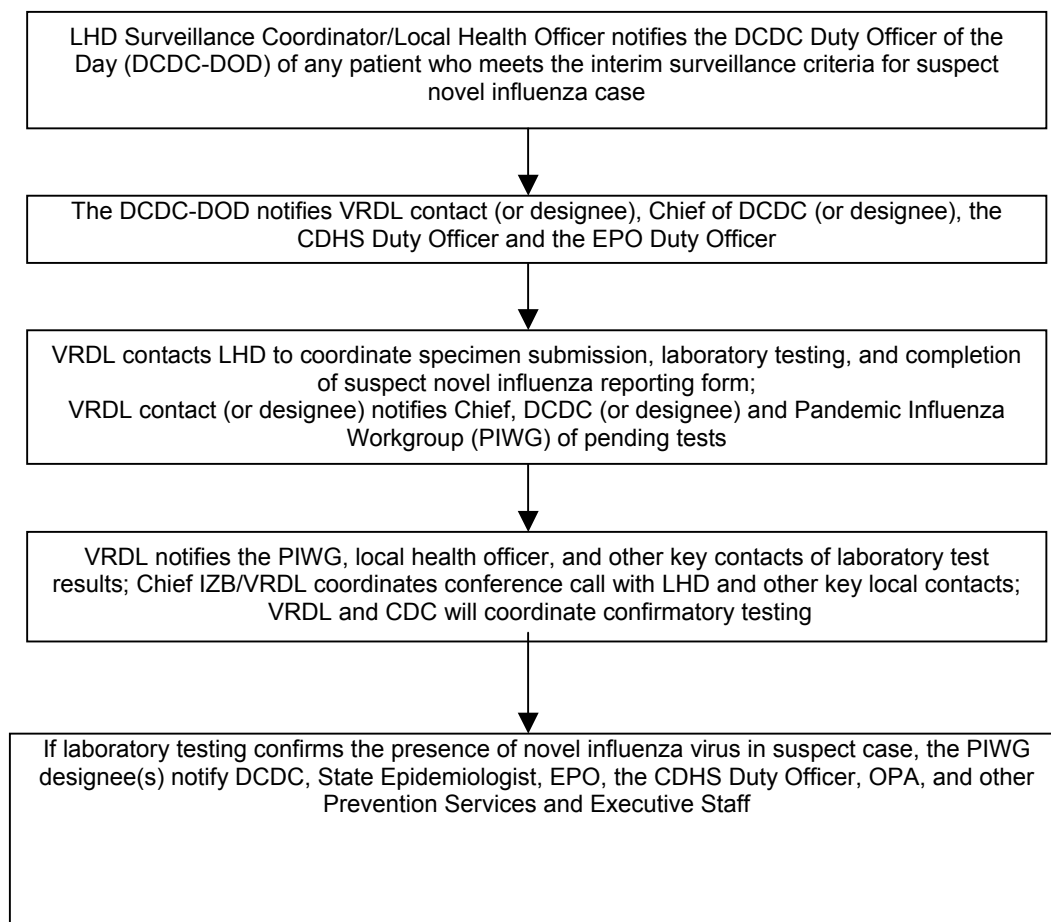
6.4 Emergency Response Notification and Activation Procedures

Medical and/or public health authorities may detect the first human case of novel influenza virus disease in California through the clinical evaluation of persons presenting with influenza-like illness (ILI¹) or upper respiratory disease.

CDC communicates updated national surveillance recommendations to states via the Health Alert Network (HAN). The Chiefs of the Immunization, Infectious Diseases, and Viral and Rickettsial Disease Laboratory (VRDL) Branches are all designated recipients of HAN communications. The CDC PIWG reviews these surveillance recommendations, provides any needed technical clarifications or revisions for application to California and distributes recommendations to LHDs and hospital-based infection control practitioners by e-mail and the California Health Alert Network (CAHAN). LHDs distribute recommendations to individual physicians via CAHAN and/or their own emergency communication mechanisms. If CDC recommendations are not forthcoming, the CDC Pandemic Influenza Workgroup develops interim surveillance recommendations and will distribute them through e-mail and CAHAN.

¹ Influenza-like illness, or ILI, is defined as fever >100°F AND cough and/or sore throat (in the absence of a known cause other than influenza).

The following flow chart illustrates the CDHS notification and initial activation procedure in response to a novel influenza virus and/or a suspect novel human influenza case in California.



The first detection of laboratory-confirmed novel influenza virus human infection in California or elsewhere in the United States, or evidence of sustained human-to-human transmission anywhere in the world, is the trigger that activates the relevant components of the CDHS emergency management organization and may trigger a CDHS Director's declaration of a public health emergency or a Governor's proclamation of a State of Emergency. The scale of the activation will be situation-specific and will be determined by the Director in consultation with the State Public Health Officer, the DCDC Chief, EPO, and the DPC.

The OES Warning Center will be notified of the activation of the JEOC. During initial activation of the JEOC, the JEOC Director will convene an internal conference call with key JEOC managers and DCDC program representatives including the PIWG to assess the current situation and determine the appropriate public health actions and priorities. DCDC will convene a conference call with all LHOs, key state agencies, and other local contacts within one day of a positive laboratory confirmation of human infection with a novel influenza virus.

DCDC will activate program activities at the RCC and may deploy a pandemic influenza assessment team to the location of the first case of identified novel influenza virus infection for on-site situation assessment and to assist in case investigation. These teams report intelligence and situation assessments directly to DCDC staff at the RCC, who report to the JECC.

6.5 Actions to Control the Pandemic and Responsible Parties

The key functional areas of the pandemic influenza response are surveillance and epidemiologic investigation, vaccine and antivirals operations, non-medical containment, surge capacity, infection control guidance to healthcare facilities, and risk communications.

During a pandemic, LHDs retain their responsibility for:

- conducting primary surveillance and reporting of cases;
- conducting primary case investigation and treatment;
- conducting primary laboratory analysis and confirmation of influenza;
- identifying sources of disease and causes of disease spread;
- preventing spread of disease through education and information;
- providing immunization, treatment, and other means of preventing spread;
- protecting communities through legal orders and enforcement if needed;
- coordinating with other public health agencies at the local and state level;
- requesting needed assistance from other local and state agencies; and
- informing and educating partner agencies and the public on public health guidance and actions needed to reduce and slow the spread of disease.

CDHS will be responsible for the following actions, as appropriate:

- assessing need for enhanced surveillance in both affected and unaffected localities and activating revised surveillance protocols, as needed (DCDC);
- activating enhanced influenza surveillance strategies that are coordinated with national surveillance objectives (DCDC);
- activating laboratory testing, ensuring appropriate capacity, and providing guidance to local laboratories (VRDL);
- assessing the need for, and activating re-prioritized laboratory testing protocols (VRDL);

- activating and deploying specialists and liaisons, or Rapid Assessment Teams, comprising state staff, to selected locations in the field as needed (DCDC, EPO);
- developing and communicating (including to the public, as appropriate) a dynamic, prioritized list of treatment and prophylaxis recommendations, including priority recipients, in coordination with the CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization Strategies and general authorities (DCDC, HISP, EPSU, OPA, JEOC/PIO);
- disseminating case and contact management protocols to ensure suspect cases are promptly identified and isolated, and contacts are located, quarantined, and monitored for symptoms, as appropriate (DCDC);
- distributing federally supplied vaccine to ensure an adequate supply to priority geographic areas and recipients (DCDC, EPSU);
- minimizing vaccine wastage by identifying priority recipients and by ensuring appropriate vaccine storage, handling and administration (DCDC, EPSU, CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization Strategies);
- activating infection control procedures and disseminating guidance to minimize transmission of influenza in homes, the community, and healthcare facilities (DCDC, L&C, Department of Social Services, Department of Mental Health);
- invoking state legal authorities to ensure availability of additional beds and alternate facilities, including licensure of, and appropriate infection control in, healthcare facilities (DCDC, L&C, Office of Legal Services [OLS]);
- invoking state legal authorities, such as the suspension of licensing requirements, to support the availability of surge clinical and hospital staffing (EPO, L&C, OLS, EMSA);
- recommending to local authorities the most feasible, effective, and enforceable methods of isolation and quarantine to prevent the spread of influenza (DCDC, L&C, OLS);
- invoking isolation, quarantine or social-distancing requirements using state legal authorities, as appropriate, and coordinating with federal authorities on measures to prevent the interstate spread of influenza (DCDC, L&C, OLS);
- coordinating with federal and local authorities on public messages to ensure that communications are consistent and accurate and ensuring that messages address anxieties, alleviate unwarranted concerns or distress, and enlist cooperation with necessary control measures (DCDC, OPA, EPO/PIO);
- promoting self-protective behaviors to diverse California communities in multiple languages and formats through the development of consistent messages and materials for distribution through LHDs, response partners and others (OPA, EPO, DCDC);

- providing training, including just-in-time training, to build public health and healthcare capacity to respond and building needed surge capacity (EPO, HRSA, DCDC);
- implementing the appropriate Governor's Standby Order to hold and control drugs and medical supplies intended for wholesale distribution, obtain necessary inventories, and coordinating the distribution of assets to the designated locations (EPO, EPSU);
- organizing and releasing state and federal public health and medical response assets (in conjunction with local officials) to include personnel, drugs and medical supplies such as assets from the Strategic National Stockpile (EPO, EPSU, EMSA);
- assessing and recommending step-down and recovery operations (DCDC);
- activating post-event surveillance to ensure control of the pandemic (DCDC); and
- continuing vaccine programs, if available, to maintain or increase immunity in the population (DCDC).

6.6 Mitigation

Mitigation activities are important elements of preparedness and provide a critical foundation across the incident management spectrum from prevention through response and recovery. Several key mitigation measures have been incorporated throughout the pandemic phase responses. During a pandemic, large scale disruption of all sectors of society is likely. Several of the key activities undertaken to mitigate the impact of a pandemic include the following:

- public education to teach basic respiratory hygiene and what might be expected during a pandemic;
- private sector and government planning for continuity of operations to handle expected absenteeism from illness, caring for household members, or fear of coming to work;
- private sector and government planning for inventory scarcity and disruption of essential supplies;
- evaluation of how much public contact is needed and alternatives to maintaining operations;
- pharmaceutical solutions such as vaccine, which cannot be relied on for the first 6-12 months; and
- social distancing measures such as wearing masks, staying home if sick, and canceling school and public events.

6.7 Recovery

Unlike other natural disasters, an influenza pandemic may last for two to three years, and occur in several waves. Recovery from an influenza pandemic begins while the pandemic is still in progress, and continues during the periods between waves and following the pandemic. The following activities are important aspects of recovery:

- providing detailed retrospective characterization of the pandemic;
- evaluating the efficacy of containment measures and emergency management strategies;
- assessing the effectiveness of vaccines and antivirals;
- preventing or minimizing subsequent waves of influenza by using current vaccine or antiviral resources; and
- incorporating mental health messages to facilitate recovery with continuance of self-care messages.

Following a pandemic, CDHS will conduct an in-depth review and critique of the response activities listed in this plan with staff and other organizations and agencies. The review will result in a formal after-action report with recommendations to improve future preparedness.

7.0 Acronyms and Abbreviations

Acronym	Definition
ACIP	Advisory Committee on Immunization Practices
BPC	Business and Professions Code
BSL	BioSafety Laboratory
BT	Bioterrorism
CAHAN	California Health Alert Network
CAHF	California Association of Health Facilities
CAHSH	California Association of Health Services at Home
CAIR	California Automated Immunization Registry
CAL/OSHA	California Occupational Safety and Health Administration
CAPHLD	California Association of Public Health Laboratory Directors
CCLHO	California Conference of Local Health Officers
CDC	Centers for Disease Control and Prevention
CDFA	California Department of Food and Agriculture
CDHS	California Department of Health Services
CDHS-DO	California Department of Health Services Duty Officer
CDHS-ERPP	California Department of Health Services Emergency Response Plan and Procedures
CEP	California Emergency Physicians
CERC	Crisis and Emergency Risk Communication
CHA	California Hospital Association
CHDP	Child Health and Disabilities Prevention Program
CHEAC	County Health Executives Association of California
CHHSA	California Health and Human Services Agency
CISP	California Influenza Surveillance Project
CMA	California Medical Association
COBBH	California Office of Binational Border Health
CPIRP	CDHS Pandemic Influenza Response Plan
CRA	Countermeasure and Response Administration
CSC	California Service Corp (State Agency)
DCA	Department of Consumer Affairs
DCDC	Division of Communicable Disease Control
DCDC-DOD	Division of Communicable Disease Control Duty Officer of the Day
DCDC-RCC	Division of Communicable Disease Control Richmond Campus Coordination Center
DEODC-OHB	Division of Environmental & Occupational Disease Control Occupational Health Branch
DMH	Department of Mental Health
DPC	Disaster Policy Council
DSS	Department of Social Services
ED	Emergency Department
EMS	Emergency Medical Services
EMSA	Emergency Medical Services Authority
EMT	Emergency Medical Technician
EOC	Emergency Operation Center
Epi-X	Epidemic Information Exchange
EPO	Emergency Preparedness Office
EPSU	Emergency Pharmaceutical Services Unit

Acronym	Definition
ESAR-VHP	Emergency System for Advance Registration of Volunteer Healthcare Professionals
EUA	Emergency Use Authorization (U.S. Food and Drug Administration)
EWIDS	Early Warning Infectious Disease Surveillance
FDA	Food and Drug Administration
FEMA	Federal Emergency Management Agency
GI	Gastrointestinal
H&S	Health and Safety
HALO	Human Assets Locator
HAN	Health Alert Network (Federal)
HCF	Healthcare Facility
HCW	Healthcare Worker
HEICS	Hospital Emergency Incident Command System
HEPA	High Efficiency Particulate Air Filter
HHA	Home Health Agency
HHS	U.S. Department of Health and Human Services
HRSA	Health Resources and Services Administration
HVAC	Heating, Ventilation, Air Conditioning
IC	Infection Control
ICP	Incident Command Post
IDB	Infectious Diseases Branch
IHSS	In Home Supportive Services
ILI	Influenza-like illness
IND	Investigational New Drug
IT	Information Technology
IZB	Immunization Branch
JAC	Joint Advisory Committee
JEOC	Joint Emergency Operations Center
JEOC-PIO	Joint Emergency Operations Center – Public Information Officer
JIC	Joint Information Center
L&C	Licensing & Certification
LHD	Local Health Department
LHO	Local Health Officer
LTCF	Long-Term Care Facility
MAC	Multi-Agency Coordinating Group
MCI	Mass Casualty Incident
MDL	Microbial Disease Laboratory
MHOAC	Medical Health Operational Area Coordinator
MMAA	Master Mutual Aid Agreement
MOU	Memorandum of Understanding
MRC	Medical Reserve Corp
NIMS	National Incident Management System
OA	Operational Area
OES	Office of Emergency Services
OHS	Office of Homeland Security
OLS	Office of Legal Services
OMS	Outbreak Management System
OPA	Office of Public Affairs

Acronym	Definition
OSHPD	Office of Statewide Health Planning and Development
PCR	Polymerase Chain Reaction
PI	Pandemic Influenza
PICU	Pediatric Intensive Care Unit
PI Liaison	Public Information Liaison
PIO	Public Information Officer
PIWG	Pandemic Influenza Work Group
PPE	Personal Protective Equipment
PSA	Public Service Announcement
PVS	Pre-Event Vaccination System
RCC	Richmond Campus Coordination Center
RDMHC	Regional Disaster Medical Health Coordinator
RDMHS	Regional Disaster Medical Health Specialist
REOC	Regional Emergency Operations Center
RLN	Respiratory Laboratory Network
SEMS	Standardized Emergency Management System
SNF	Skilled Nursing Facility
SNS	Strategic National Stockpile
SOC	State Operations Center
VAERS	Vaccine Adverse Event Reporting System
VFC	Vaccines for Children
VIS	Vaccine Information Statement
VRDL	Viral and Rickettsial Disease Laboratory
Web-CMR	Web Confidential Morbidity Report
WHO	World Health Organization

Appendix 1 – Influenza and Pandemic Influenza Surveillance and Epidemiology

1.1 Introduction

1.1.1 Global/national influenza surveillance

In the United States, the Centers for Disease Control and Prevention (CDC) coordinates national influenza surveillance. National influenza surveillance consists of four components:

- laboratory surveillance;
- outpatient influenza-like illness (ILI) surveillance;
- pneumonia- and influenza-related mortality surveillance; and
- determination of relative influenza activity in individual states.

1.1.2 California Influenza Surveillance

ILI and Novel Influenza Surveillance

Influenza is not a reportable disease in California because of the large number of cases that occur each year with a non-specific clinical presentation and no routine laboratory confirmation. However, CDHS collaborates with academic, public, and private institutions to obtain information from multiple sources about disease activity. During the influenza season (Week 40 through Week 20), CDHS, through a collaborative effort of the Viral and Rickettsial Disease Laboratory (VRDL), the Immunization Branch (IZB), and the Infectious Diseases Branch (IDB), monitors influenza illness activity using the following surveillance systems:

- hospitalizations for pneumonia and influenza (Northern and Southern California Kaiser Permanente);
- antiviral prescription data (Northern and Southern California Kaiser Permanente);
- outpatient ILI (CDC Influenza Sentinel Providers);
- California emergency department visit data (California Emergency Physicians);
- severe pediatric influenza and pediatric influenza-associated deaths;
- surveillance of respiratory outbreaks in long-term care facilities (LTCF);
- surveillance for human avian influenza;
- surveillance for vaccine adverse events; and
- ILI surveillance along the California-Baja California border through the Early Warning Infectious Disease Surveillance (EWIDS) and Border Infectious Disease Surveillance (BIDS) Programs.

Influenza Laboratory Surveillance

- **Sentinel Laboratories** provide data on the number of laboratory-confirmed influenza and other respiratory virus detections, and virus isolations. Nineteen laboratories report these data weekly.
- **Respiratory Laboratory Network (RLN)** encompasses 22 local public health laboratories in California. Twenty RLN laboratories offer enhanced diagnostic testing for several respiratory pathogens, including influenza A and B viruses, respiratory syncytial virus, parainfluenza virus, and adenovirus. Twenty-two RLN laboratories offer polymerase chain reaction (PCR) testing for influenza A and B.
- **CDHS Viral & Rickettsial Disease Laboratory (VRDL)** serves as a statewide reference laboratory that offers diagnostic testing for influenza using isolation, PCR, and serologic testing.

The Division of Communicable Disease Control (DCDC) has a Pandemic Influenza Work Group (PIWG) consisting of representatives of the VRDL, IZB, and IDB. The team meets weekly throughout the influenza season to review surveillance data, discuss the level of influenza activity, review individual cases and outbreaks, review vaccine supply distribution and allocation, work on communication activities, coordinate efforts with the Office of Public Affairs (OPA), and Emergency Preparedness Office (EPO) Risk Communication Section, and to assign tasks when action is needed.

For more complete information on CDHS interpandemic influenza surveillance activities, see Attachment 1A.

1.2 Objectives

The objectives of the CDHS Pandemic Influenza Surveillance Program are to:

- monitor the emergence of a novel influenza virus in human populations and detect the first appearance of a novel influenza virus in California;
- describe the epidemiologic and clinical features of an influenza outbreak; and
- provide critical surveillance data and facilitate response activities.

1.3 Assumptions and Planning Principles

1.3.1 Influenza Illness Surveillance

- An essential requirement of an effective statewide pandemic influenza surveillance system is a well-functioning inter-pandemic influenza surveillance system.
- Surveillance needs will expand and change as an influenza pandemic evolves from the initial stages when a novel influenza strain is first identified in one or more persons to when a pandemic, with efficient human-to-human transmission, actually occurs. The surveillance needs will differ depending on where disease has been identified, whether there is coexisting disease among poultry or other animals, whether and how efficiently

transmission occurs between people, and whether disease outbreaks have occurred in the United States or other countries.

- Surveillance data will be critical to help guide implementation of control measures such as restricting travel, closing schools and canceling public gatherings, initiating antiviral and vaccine usage in defined target groups, assessing the impact of a pandemic on the healthcare system, and assessing the social and economic impact on society.
- During a pandemic, stakeholders, the media, and the public will demand timely surveillance data.
- California shares many social and economic ties with Baja California, Mexico. There are more than 200 million northbound border crossings in a year. When individuals with an infectious disease or their contacts cross the international border (i.e., binational cases and contacts), binational cooperation is necessary for public health follow-up. During the phases of pandemic influenza, close collaboration between California and Baja California influenza surveillance systems is essential to monitor influenza activity and guide coordinated response strategies in the border region.
- In the interpandemic and early stages of a pandemic, before community transmission is established, CDHS and local health departments (LHDs) will monitor individual cases of suspected and confirmed novel virus infection, including relevant demographic and clinical information. However, once community transmission is established and monitoring numbers of suspected and confirmed cases becomes overwhelming, CDHS and LHDs will collect only aggregate numbers of suspected and confirmed cases by county, as well as other important morbidity and mortality markers such as numbers of hospitalizations and deaths.
- Once a pandemic is well under way and community transmission of novel virus infection is established, supplies of rapid antigen testing and reagents for immunofluorescence assays and PCR will likely be depleted. At this stage, surveillance for novel virus infection will primarily rely on clinical diagnoses made in outpatient clinics, emergency departments, inpatient wards, and intensive care units, with assistance from the LHD.

1.4 CDHS Influenza Surveillance Activities by WHO Pandemic Phase

1.4.1 WHO Phase 1 and Phase 2 - Interpandemic Period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals

1.4.1.1 Influenza Illness Surveillance

- CDHS will continue all interpandemic surveillance activities as described above and in Attachment 1A.
- CDHS will encourage influenza sentinel providers to perform year-round reporting of ILI activity.
- In conjunction with local public health laboratories, CDHS will explore the development of a laboratory-based surveillance system for cases of severe unexplained pneumonia.

- CDHS will explore the development of an enhanced surveillance system for ILI in sentinel school-based clinics and health offices.
- CDHS will explore the development of an enhanced surveillance system for pneumonia and influenza-associated deaths.
- CDHS and LHDs will work closely with private sector healthcare organizations and healthcare providers to implement active surveillance in emergency departments, inpatient wards, and intensive care units, since the first cases of novel virus infection in the United States will likely be evaluated in these settings.
- During the interpandemic and early stages of a pandemic, before community transmission is established, CDHS will encourage the use of influenza rapid diagnostic tests, immunofluorescence assays, and PCR to 1) detect the first case(s) of novel virus infection in California; and 2) target containment strategies such as isolation and quarantine, contact tracing and use of limited vaccine and antivirals in the populations-at-risk.
- CDHS will evaluate and implement an outbreak management system to assist with case management, case ascertainment, case reporting, surveillance, and data analysis.
- CDHS will explore the possibility of assessing rates of hospitalization for pneumonia and influenza activity in sentinel hospitals, such as community hospitals and children's hospitals.
- VRDL will work to expand capacity for novel virus testing to sentinel local public health laboratories, including providing training, technical assistance, and reference/validation testing. CDHS will ask sentinel local public health laboratories to report testing for any suspect avian influenza cases and forward clinical specimens to VRDL for concurrent testing.
- CDHS will coordinate with the California Department of Food and Agriculture (CDFA) and California Department of Fish and Game (CDFG) on enhanced surveillance and reporting of novel influenza virus detections in poultry workers, commercial or private poultry flocks, and in wild birds in order to identify disease activity in animal populations and characterize the human health threat.
- CDHS will share influenza surveillance data and epidemiological information in a timely manner with bordering states and Baja California public health officials, as appropriate.

1.4.2 WHO Phase 3 and Phase 4 - Pandemic Alert Period: Human infection with no or very limited human-to-human transmission

1.4.2.1 Influenza Illness Surveillance

- Upon laboratory confirmation of the first case of novel influenza virus in California, CDHS will develop guidance to LHDs on surveillance, case detection, contact tracing, and infection control. CDC will coordinate disease control activities and provide technical assistance to LHDs with any confirmed cases of novel influenza virus infection.

- CDHS will actively monitor any changes in recommendations and guidelines for surveillance and diagnostic testing from CDC (e.g., revision of the case definition, screening criteria, case report form, or diagnostic testing algorithm) and implement as necessary.
- CDHS will communicate with LHDs via weekly electronic communications, *CD Brief*, the VRDL California Influenza Surveillance Project website, and conference calls to share information on surveillance criteria, case management, specimen collection, and appropriate testing.
- CDHS will work with LHDs to detect and monitor persons who have recently traveled to areas where the novel virus is identified and who present with clinical illness consistent with influenza. CDHS will provide technical assistance and guidance to assess and report suspect cases of novel virus infection.
- CDHS will encourage all current influenza sentinel providers to report data year-round and remind sentinel providers of the enhanced surveillance activities for human cases of novel influenza virus and of the need to report suspect cases to their LHD for further evaluation and testing.
- CDHS will recruit sentinel physicians to report ILI activity, collect respiratory specimens, and submit them to VRDL for testing.
- CHDS will maintain all other existing enhanced surveillance systems.
- CDHS will explore recruiting pharmaceutical vendors or large pharmacy chains to report antiviral prescriptions filled. CDHS will also explore using Medi-Cal pharmacy paid claims data to determine antiviral drug usage.
- CDHS will encourage reporting of all suspect human cases of the novel influenza virus or cases of clinical illness consistent with a novel influenza virus through online confidential morbidity reports (Web-CMR), when operational.
- CDHS will work with LHDs to utilize an outbreak management system for case investigations, case management, case ascertainment, case reporting, surveillance, and data analysis.
- CDHS will generate weekly reports of statewide influenza activity and make current surveillance data available to all participating agencies as well as CDC, LHDs, EPO, Joint Emergency Operations Center Public Information Officer (JEOC PIO), and OPA.
- CDHS will review contingency plans to further enhance influenza surveillance if efficient person-to-person transmission of the novel virus is confirmed, including training additional personnel on surveillance, case detection, contact tracing, and infection control issues.
- CDHS will continue to coordinate with CDFA and CDFG on enhanced surveillance and reporting of novel influenza virus detections in poultry workers, commercial or private poultry flocks, and in wild birds in order to identify disease activity in animal populations and characterize the human health threat.

- CDHS will communicate current surveillance data, epidemiologic information, and changes in recommendations and guidelines for surveillance and diagnostic testing from CDC with Baja California public health officials, as appropriate.

1.4.2.2 Laboratory surveillance

- CDHS will increase the supply of reagents and personnel for VRDL in order to develop diagnostic assays that are critical to surveillance and monitoring of containment in a pandemic, including antiviral resistance testing, neutralizing antibody assays to test for immunity to the novel virus, and egg-based culture methods to isolate novel viruses that are difficult to grow by standard culture methods.
- CDHS will increase laboratory testing capacity that will be critical in a pandemic, including procuring laboratory equipment and supplies, re-certifying the non-traditional labor pool, and redirecting and hiring of additional laboratory employees.
- VRDL will communicate frequently with CDC concerning updated diagnostic algorithms and available laboratory reagents for novel virus testing (e.g., specific primers and probes), communicate results on suspect novel influenza virus cases to CDC, and expedite specimen shipping as needed.
- VRDL will work to expand capacity for novel virus testing to sentinel local public health laboratories, including providing training, technical assistance, and reference/validation testing. CDHS will ask these local public health laboratories to forward clinical specimens to VRDL for concurrent novel virus testing.
- CDHS will encourage submission of clinical specimens from ILI cases from all sources (private and public clinics, including sentinel providers, and hospitals) and facilitate subtyping of influenza A viruses at either the local or state level. VRDL will perform novel virus testing on all suspect cases of the novel influenza virus, and will encourage/support testing capacity at local public health laboratories.
- VRDL will report and submit to CDC any influenza A virus that cannot be subtyped. Clinical and public health laboratories will not attempt isolation on specimens from cases of suspect novel influenza virus because of potential risk of spread to domestic poultry. CDHS will provide detailed guidance on alternative diagnostic testing options, including rapid antigen detection, immunofluorescence assays, and PCR.
- VRDL will encourage all participating sentinel laboratories and the RLN to increase testing for influenza and to report data to VRDL year-round.

1.4.3 WHO Phase 5 - Substantial Pandemic Risk: Larger clusters but still limited human-to-human transmission; sustained community transmission is possible

The most important role of surveillance during this phase is to identify the timing, location, and extent of the novel influenza strain infection in California in order to guide implementation of outbreak control and other response activities.

1.4.3.1 Influenza Illness Surveillance

- CDHS will communicate frequently with CDC to monitor any changes in recommendations and guidelines for surveillance and diagnostic testing, including guidance on triaging specimens for testing and choosing which isolates to send to CDC. CDHS will immediately inform LHDs of new recommendations.
- CDHS will recommend that all or select suspect cases of ILI be tested for influenza at either the institutional, local, or state level. If testing confirms influenza, VRDL and local public health laboratories with novel virus testing capacity will perform further testing as indicated. For example, targeted novel virus testing might be performed on cases occurring in an outbreak setting, cases with unusual or severe clinical illness, and cases with epidemiologic risk (e.g., recent travel to a country known to be affected with the novel influenza virus, recent contact with a suspect or confirmed human case infected with the novel virus, or is employed in an occupation with a high-risk of exposure). Appropriate information gathered will be posted to the California Health Alert Network (CAHAN) and distributed using the appropriate alert level, as needed.
- CDHS will work closely with LHDs to manage new suspect cases, provide further confirmatory testing, and implement containment strategies to prevent or limit local spread (e.g., isolation and quarantine, antiviral treatment, and/or prophylaxis).
- CDHS will provide technical assistance to guide expanded testing on specific cases that represent risk of spread of the novel virus infection in the community, including those who have an epidemiologic link to infected cases (e.g., recent contact with a suspect or confirmed human case infected with the novel virus) or are hospitalized. CDHS will communicate with CDC concerning management, reference laboratory testing, and containment strategies in these cases.
- CDHS will communicate with sentinel providers the most current surveillance criteria for cases of human novel virus infection, and the need to report data year-round and submit clinical specimens on ILI cases.
- CDHS will activate all other existing enhanced surveillance systems to report data year-round.
- CDHS will generate weekly reports of statewide influenza activity and make current surveillance data available to all participating agencies as well as CDC, LHDs, EPO, JEOP-PIO, and OPA.
- CDHS will allocate additional personnel as needed to assist with surveillance activities, such as identifying IT resources needed to assist in and developing or modifying a database for influenza surveillance.
- CDHS will communicate the most current information on influenza epidemiology to Baja California public health officials, as appropriate.

1.4.3.2 Laboratory surveillance

- VRDL will continue frequent communication with CDC as described in Phase 3-4 concerning updated diagnostic algorithms and available laboratory reagents for novel virus testing (e.g., specific primers and probes), communicate results on suspect novel influenza virus cases to CDC, and expedite specimen shipping as needed.
- Using e-mail, CAHAN, Epi-X, broadcast fax, and statewide conference calls, VRDL will communicate with local public health laboratories and other stakeholders regarding the detection and circulation of novel virus worldwide and in the United States, and will provide detailed guidance on updated case definitions, diagnostic algorithms, and laboratory infection control issues. As the pandemic progresses and guidelines and testing algorithms are revised, VRDL will communicate these changes to local public health laboratories.
- VRDL will continue to encourage expanded testing for novel virus to interested local public health laboratories as described in Phase 3-4. In addition, VRDL will report and send to CDC any influenza A virus that cannot be subtyped.
- CDHS will encourage all participating sentinel laboratories and the RLN to increase testing for suspect cases of novel influenza with non-culture methods and to report data to VRDL.
- CDHS will maintain expanded critical laboratory testing capacity.
- CDHS will seek to maintain expanded diagnostic testing including antiviral resistance testing, neutralizing antibody assays to test for immunity to the novel virus, and egg-based culture methods to isolate novel viruses that are difficult to grow by standard culture methods.

1.4.4 WHO Phase 6 - Pandemic Period: Increased and sustained transmission in the general population

The goals of surveillance in California in the “Pandemic Period” include:

- monitoring the epidemiology and impact of the pandemic in California; and
- sustaining capacity to perform laboratory-based surveillance is also an important priority, as influenza viruses may undergo antigenic drift or develop resistance to antiviral agents.

1.4.4.1 Influenza illness surveillance:

- CDHS will support LHDs, public and private medical providers (including sentinel providers), hospitals, and other stakeholders to maintain surveillance efforts for cases of novel virus infection. As the pandemic progresses and laboratory services become overwhelmed, public and private medical providers (including sentinel providers) and hospitals may be asked to selectively submit clinical specimens as indicated by CDC guidance. If laboratory supplies and reagents are exhausted, surveillance for novel virus infection will rely on a presumptive clinical diagnosis made by clinicians.

- Once community transmission is established, CDHS will continue reporting cases (through Web-CMR, when operational) and request minimal daily reports from LHDs to obtain a statewide tally of number of cases associated with novel virus infection, morbidity, and mortality. The information CDHS requests will depend on the epidemiology of disease at the time of the pandemic. Such reports might include:
 - number of clinically suspected cases;
 - number of laboratory confirmed cases;
 - number hospitalized due to novel virus infection; and
 - number of deaths attributed to novel virus infection.
- As resources are available, CDHS in collaboration with CDC may conduct special studies to:
 - describe unusual clinical syndromes;
 - describe unusual pathologic features associated with fatal cases;
 - determine efficacy of vaccination or chemoprophylaxis, if vaccine is available;
 - assess antiviral effectiveness in circulating strains to help refine antiviral recommendations and target high risk groups; and/or
 - assess the effectiveness of control measures such as school and business closures.
- CDHS will analyze available data to determine which population groups are at greatest risk, and, in conjunction with CDC, to further refine and revise priority groups for immunization as vaccine and antiviral availability increases.
- CDHS will generate weekly reports of statewide activity and share current surveillance data with all participating agencies including CDC, LHDs, EPO, JEOC-PIO, and OPA.
- CDHS will communicate the most current information on influenza surveillance, epidemiology, and (potential) control efforts to Baja California public health officials.

1.4.4.2 Laboratory surveillance

- As resources permit, CDHS will continue to encourage all participating sentinel laboratories and the RLN to test for influenza with non-culture methods. Depending on CDC guidance, CDHS may ask these laboratories to forward specimens to VRDL or local public health laboratories with novel virus testing capacity for further testing.
- As indicated by CDC guidance and as resources permit, VRDL will perform strain characterization of incoming specimens and isolates in order to detect antigenic drift variants and reassortant viruses that could limit the efficacy of vaccines produced against the original pandemic strain.

- As resources permit, VRDL will continue to perform testing critical to ongoing surveillance and monitoring, including antiviral resistance testing and neutralizing antibody assays to test for immunity to the novel virus.

1.4.5 WHO Postpandemic Period

The goals of postpandemic surveillance are to:

- provide a detailed retrospective characterization of the pandemic; and
- evaluate the efficacy of containment measures and emergency management strategies.

CDHS will:

- review death certificates statewide for influenza-related pneumonia and influenza deaths;
- conduct retrospective studies of vaccine efficacy;
- conduct validation studies of influenza illness reporting;
- conduct retrospective studies of the efficacy of containment measures;
- provide frequent updates to the JEOC for tracking and monitoring of postpandemic activities; and
- conduct a retrospective assessment of cross-border coordination with Mexican public health officials.

1.5 Epidemiologic Investigation

1.5.1 Introduction

Epidemiologic investigations should be initiated to identify how suspected human cases of novel influenza virus became infected, assess the clinical impact of the disease, and determine the risk that infected persons, or their environment, may represent for others. Proper contact investigations should also be initiated in order to prevent further transmission, identify potential new cases, and provide appropriate treatment and/or clinical treatment. Based on these epidemiologic investigations, preventive measures, including non-medical containment strategies, may be identified or revised and specific actions (e.g., identification and prophylaxis treatment of contacts) evaluated and carried out.

1.6 Objectives

The objectives of the CDHS Pandemic Influenza Epidemiology Program are to:

- ensure suspect novel human influenza cases are isolated, and source of exposure (animal vs. human) are determined in the pandemic alert and early phases of a pandemic;

- conduct epidemiologic investigations of suspect human influenza cases to identify at-risk populations and current clinical characteristics of disease, and assess likely human-to-human transmission; and
- conduct epidemiologic research investigations to evaluate phase-specific control measures.

1.7.1 Assumptions and Planning Principles

- In the pandemic alert period and in the early phases of the pandemic, identifying the source of infection (animal vs. environment vs. human) for new cases will be a critical activity that will provide support for decisions about containment strategies. The need for such studies once the pandemic is underway will be determined on a case-by-case basis.
- The types of epidemiologic studies (those addressing clinical characteristics, risk factors, the probability of transmission among humans, treatment efficacy studies) conducted will differ during different phase of the pandemic.

1.8 CDHS Epidemiologic Investigation Activities by WHO Pandemic Phase

1.8.1 WHO Phase 1 and Phase 2 - Interpandemic Period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals

1.8.1.1 Epidemiologic Investigation

- CDHS will develop and implement criteria and protocols for epidemiologic investigation of influenza outbreaks, influenza case clusters with unusual clinical presentation (e.g., unusual severity), and clusters of unexplained pneumonia (these latter cases may be sentinel indicators for unusual influenza activity).
- CDHS will enhance and expand capacity at the local and state levels to conduct case investigations and epidemiologic investigations in inter-pandemic and pandemic alert phases, inventory current capacity, develop forecasts of future capacity needs under different pandemic scenarios, and identify gaps.
- CDHS will evaluate and implement an outbreak management system for case investigations, case management, case ascertainment, case reporting, surveillance, and data analysis.
- CDHS will develop protocols that clearly define and designate who will conduct epidemiologic studies in phases 3-6 and how they will be coordinated (e.g., coordinating between local, state, and federal investigations).
- CDHS will assist in building capacity and determining current skill levels, conducting drills and exercises in case investigations, and conducting epidemiologic investigations during the inter-pandemic period.

- CDHS will identify and implement funding streams and training strategies to ensure that epidemiologic capacity at the state and local level is consistent with current and future needs.
- CDHS will collaborate with CDC and Baja California health officials in the epidemiologic investigation of binational influenza cases and outbreaks, as appropriate.

1.8.2 WHO Phase 3 and Phase 4 - Pandemic Alert Period: Human infection with no or very limited human-to-human transmission

1.8.2.1 Epidemiologic Investigation

- CDHS, in coordination with CDC and the DCDC Pandemic Influenza Work Group (PIWG) recommendations on community disease containment measures, will develop, distribute, and implement case management protocols to ensure suspect human cases are promptly identified, isolated, and source(s) of exposure (animal vs. human) determined. CDHS will ensure protocols are distributed to LHDs, and to settings where cases (and their contacts) might be diagnosed.
- CDHS, in collaboration with CDC and LHDs, will conduct, direct, coordinate, or provide guidance on epidemiologic investigations of human cases to identify the populations at risk, the current clinical characteristics of disease, and the risk that infected persons or their environment may pose to others, including an assessment of likely human-to-human transmission.
- CDHS, working with LHDs, will use an outbreak management system for case investigations, case management, case ascertainment, case reporting, surveillance, and data analysis.
- CDHS will coordinate with CDC on studies of viral shedding to determine the infectious and incubation periods for use in defining the duration of isolation and quarantine.
- CDHS will collaborate with CDC and Baja California health officials in the epidemiologic investigation of binational influenza cases and outbreaks, as appropriate.
- CDHS will summarize and distribute study results to the PIWG for use in assessing recommendations regarding the application and utility of non-medical containment measures. The PIWG will provide scientific review of results or will identify subject matter experts to provide scientific review of results, as needed.
- CDHS will monitor investigation and management resources; as resources permit, CDHS will assess and enhance epidemiologic capacity to support expanded activities.

1.8.3 WHO Phase 5 - Substantial Pandemic Risk: Larger clusters but still limited human-to-human transmission; sustained community transmission is possible

1.8.3.1 Epidemiologic Investigation

- CDHS, in coordination with CDC and the PIWG, will review and revise case management protocols to reflect current recommendations and epidemiologic data.

- CDHS will continue epidemiologic investigations and other special clinical studies, as warranted.

1.8.4 WHO Phase 6 - Pandemic Period: Increased and sustained transmission in the general population

1.8.4.1 Epidemiologic Investigation

- CDHS will continue situation-specific epidemiologic investigations and other special clinical studies, as warranted.

Attachment 1A - Influenza and Pandemic Influenza Surveillance

1A.1 Global/national influenza surveillance

In the United States, CDC coordinates national influenza surveillance. National influenza surveillance consists of four components: laboratory surveillance, outpatient influenza-like illness (ILI) surveillance, pneumonia- and influenza-related mortality surveillance, and determination of relative influenza activity in individual states. State and local health departments assume primary responsibility for carrying out the epidemiologic and laboratory surveillance components. Current surveillance activities include:

- Laboratory-based surveillance: Approximately 120 laboratories in the United States report the number and type of influenza viruses isolated each week, and send specimens to CDC for antigenic and genetic analysis. CDC updates this information weekly on the [CDC influenza surveillance website \(www.cdc.gov/flu/weekly/fluactivity.htm\)](http://www.cdc.gov/flu/weekly/fluactivity.htm).
- State and territorial epidemiologists report their level of influenza activity each week as “widespread,” “regional,” “sporadic,” or “no activity.” CDC updates this information weekly on the CDC influenza surveillance website.
- CDC influenza sentinel provider network: A voluntary, national network of approximately 1400 medical providers reports the number of patients presenting with ILI, age group, and the total number of patient visits for all causes each week. CDC updates ILI visit activity weekly on the CDC influenza surveillance website.
- U.S. Cities Mortality Reports: Vital statistics offices from 122 U.S. cities report weekly the percentage of total deaths caused by pneumonia and influenza as recorded on death certificates.

1A.2 California Influenza Surveillance

Influenza is not a reportable disease in California because of the large number of cases that occur each year with a non-specific clinical presentation and no routine laboratory confirmation. However, CDHS collaborates with public, academic, and private institutions to obtain information from multiple resources about disease activity. During the influenza season (Week 40 – Week 20), CDHS’ Viral and Rickettsial Disease Laboratory (VRDL), Immunization Branch (IZB), and Infectious Diseases Branch (IDB) jointly monitor influenza illness activity from the following surveillance systems:

- Hospitalizations for pneumonia and influenza from Northern and Southern California Kaiser Permanente (estimated membership: 6 million persons): This surveillance system defines “flu admissions” as inpatient hospitalizations admitted with the text field diagnoses of “flu,” “influenza,” or “pneumonia.” The percentage of influenza admissions is defined as the number of hospitalizations fulfilling the above criteria over the total number of hospital admissions for the same day, excluding admissions for pregnancy, admissions for inpatient surgeries, labor and delivery, birth, and outpatient procedures. The baseline influenza admission percentage, reflective of year-round pneumonia admissions, is estimated to be approximately three to five percent. Influenza admissions are tracked weekly and a summary is distributed electronically to LHDs and other public

health stakeholders. CDHS posts these data to the [VRDL California Influenza Surveillance Project](http://www.dhs.ca.gov/ps/dcdc/VRDL/html/FLU/fluintro.htm) website (www.dhs.ca.gov/ps/dcdc/VRDL/html/FLU/fluintro.htm)

- Antiviral Prescription Data (Northern and Southern California Kaiser Permanente): Kaiser Permanente reports weekly the number of prescriptions its outpatient pharmacies fill for influenza antiviral drugs (amantadine, rimantadine, zanamivir, and oseltamivir). Baseline amantadine usage is assumed to be present year-round for disorders such as Parkinson's disease. CDHS tracks antiviral usage weekly and distributes a summary to LHDs and other public health stakeholders via the "CD Brief" and the [VRDL California Influenza Surveillance Project](http://www.dhs.ca.gov/ps/dcdc/VRDL/html/FLU/fluintro.htm) website (www.dhs.ca.gov/ps/dcdc/VRDL/html/FLU/fluintro.htm).
- CDHS' state influenza sentinel provider surveillance coordinator performs the following:
 - Monitors sentinel provider data weekly for completeness and errors.
 - Provides feedback and maintains contact with sentinel influenza providers weekly to encourage reporting, follow-up on unusual reports, and monitoring for completeness and errors.
 - Encourages year-round reporting of influenza activity from sentinel providers.
 - Encourages sentinel providers to submit specimens for viral culture to VRDL.
- Outpatient Influenza-like Illness (CDC Influenza Sentinel Providers): California has approximately 145 sentinel providers (meeting the CDC goal of 1/250,000 population) who report the number of outpatient visits for ILI, age group, and total number of outpatient visits per week. CDHS tracks the percentage of ILI visits weekly and distributes a summary to LHDs and other public health stakeholders via the "CD Brief" and the [VRDL California Influenza Surveillance Project](http://www.dhs.ca.gov/ps/dcdc/VRDL/html/FLU/fluintro.htm) website (www.dhs.ca.gov/ps/dcdc/VRDL/html/FLU/fluintro.htm). Sentinel providers also receive a weekly electronic update that summarizes sentinel provider ILI activity both statewide and regionally.
- California Emergency Physicians (CEP) Emergency Department Visit Data: In 2004, CDHS began collaborating with the California Emergency Physicians (CEP) and its physician practice partner, MedAmerica, to assist in the monitoring of ILI activity at 49 emergency departments (approximately 2 million patient visits annually) statewide. Through MedAmerica's surveillance system, "California Flu Watch," CEP electronic billing data is used to capture specific ICD-9 codes that may identify ILI, including presence of fever plus cough, sore throat, upper respiratory illness, or nasal congestion. ILI activity is subsequently analyzed by temporal trends, age groups, and regional activity. Because of the lag-time (approximately two weeks) between the emergency department visits and compilation of the billing data, the correlation with other influenza surveillance systems may not be timely.
- Severe pediatric influenza and pediatric influenza –associated deaths: CDHS conducts enhanced surveillance for pediatric cases of laboratory-confirmed influenza that have been hospitalized in a pediatric intensive care unit (PICU) or have died. Each year, CDHS requests that infection control practitioners at the 26 hospitals in California with a

PICU report any cases meeting the following definition: 1) 0-17 years; 2) have confirmed influenza by laboratory testing; and 3) have been hospitalized in the PICU or expired at any location (e.g., hospital, emergency department, home). The infection control practitioners report their cases to LHDs and CDHS. In addition, CDHS sends participating infection control practitioners and medical providers a weekly electronic update of statewide and regional activity for severe pediatric influenza and influenza-associated deaths.

- Surveillance of respiratory outbreaks in long-term care facilities (LTCF): Outbreaks in LTCFs are often the first sign of influenza activity in a community. CDHS conducts enhanced surveillance for respiratory outbreaks in LTCF. Each year, CDHS sends a guidance document for managing respiratory outbreaks to all LTCFs in California with a reminder that they are required to report clusters of respiratory illness to their LHD and L&C district office (22 CCR § 72539 and 72541). LHDs collect basic information regarding the timing and duration of outbreaks, any respiratory illness-associated hospitalizations or deaths, and numbers of residents and staff who received influenza vaccination or antiviral medications. LHDs forward summary data to CDHS. CDHS encourages LHDs to collect specimens for diagnostic testing at either local public health laboratories or VRDL.
- Surveillance for human avian influenza: Since the first reports of large scale outbreaks of avian influenza A (H5N1) in domestic poultry in Asia in late 2003, CDHS has maintained enhanced surveillance for human cases of avian influenza using surveillance criteria recommended by CDC. CDHS has developed screening guidelines, a case definition, a case screening form, an extended case report form, a diagnostic testing algorithm, and an electronic database to track suspect cases, and makes the case report forms widely available through the VRDL California Influenza Surveillance Project website and other venues. CDHS also periodically distributes reminders and updates regarding the ongoing epidemic in Asia. CDHS reminds LHDs to report any cases that meet surveillance criteria to CDHS for consultation about case management and for help with expedited PCR testing for H5 at designated local public health laboratories or VRDL.
- Surveillance for Vaccine Adverse Events: CDHS monitors reports of vaccine adverse events and forwards copies to the National Vaccine Adverse Event Reporting System (VAERS). Periodically, CDHS analyzes the data to identify increased frequency and types of complaints.

1A.3 Laboratory Surveillance

- Sentinel Laboratories: CDHS collects data on the number of laboratory-confirmed influenza and other respiratory virus detections and isolations from 19 laboratories on a weekly basis. Participants include hospital, academic, private, and public health laboratories located throughout California, including Kaiser Permanente Northern California Regional Laboratory (19 sites) and Kaiser Permanente Southern California Regional Laboratory (11 sites). Most of these laboratories have contributed data to the California Influenza Surveillance Project since 1998.
- Respiratory Laboratory Network (RLN): The RLN encompasses 22 local public health laboratories. Twenty RLN laboratories offer enhanced diagnostic testing with the “R-

mix” shell vial assay, which detects several respiratory pathogens, including influenza A and B viruses, respiratory syncytial virus, parainfluenza virus, and adenovirus. Twenty-two RLN laboratories offer PCR testing for influenza A and B.

- CDHS Viral & Rickettsial Disease Laboratory (VRDL): VRDL serves as a statewide reference laboratory that offers diagnostic testing for influenza and a broad array of other respiratory pathogens using isolation, PCR, and serologic testing. VRDL assists with diagnostic testing in a variety of settings, including institutional or community respiratory outbreaks, individual cases of severe respiratory illness, cases that meet surveillance criteria for avian H5N1 influenza, and isolation, subtyping, and strain characterization of viruses from cases of ILI submitted by sentinel providers. VRDL provides diagnostic testing free-of-charge.
- DCDC Pandemic Influenza Work Group (PIWG): The DCDC Pandemic Influenza Work Group (PIWG) consists of representatives of the VRDL, IZB, and IDB. The team meets weekly throughout the influenza season to review surveillance data, discuss the level of influenza activity, review individual cases and outbreaks, review vaccine supply distribution and allocation, work on communication activities, coordinate efforts with OPA, and assign tasks when action is needed.

1A.4 CDHS Efforts to Improve influenza Surveillance in California

- Intensifying recruitment to the CDC influenza sentinel provider network to maintain the current ratio of one provider for every 250,000 population: California has an estimated population of 36 million people, and requires 145 sentinel providers to meet CDC recommendations. Efforts to improve sentinel provider recruitment include:
 - Providing influenza rapid test kits to sentinel providers who do not otherwise have laboratory diagnostic testing available (e.g., student health centers, community clinics, mobile clinics, and private clinics not associated with a hospital laboratory). In the pilot year of the program in 2004-2005, CDHS recruited 50 additional sentinel providers in the first few months.
 - Encouraging sentinel providers to report ILI activity to a coordinator at their LHD, who can monitor reporting and encourage sentinel providers who are not reporting. As the primary contact for the sentinel provider, the LHD coordinator reports all ILI activity from his or her county to CDHS, and provides all laboratory results to the sentinel providers. Using local coordinators encourages LHDs to become involved in influenza surveillance in their region and to be viewed as the “influenza resource” for their communities.
- Focusing recruitment efforts on counties with low ratios of sentinel providers for their populations and on types of providers underrepresented in the program: Recruitment efforts in 2004-05 focused on pediatricians, who were underrepresented. Infants, toddlers, and school-age children are thought to be the primary population to introduce the spread of influenza into a community, and may often be the first population evaluated in outpatient settings.

Appendix 2 - Laboratory Capacity

This appendix addresses laboratory diagnostic capacity. Laboratory surveillance is covered separately in Appendix 1 - Influenza and Pandemic Influenza Surveillance and Epidemiology.

2.1 Introduction

Because influenza viruses are constantly changing, strong laboratory-based surveillance will be critical through all stages of the pandemic to monitor the level of disease activity and changes in virus strain. Timely identification of circulating or novel virus strains is equally important for pandemic detection and vaccine preparation. During the earliest stages of the pandemic, public health and hospital laboratories are likely to receive a large number of specimens for testing. Planning for laboratory surge capacity and the availability of diagnostic reagents will be essential for timely and effective testing. Once a pandemic is underway and the virus is widespread, laboratory confirmation for each case will not be necessary and testing priorities will likely focus on a subset of cases (e.g., severely ill cases, clusters of cases, or cases refractory to antiviral treatment).

2.2 Objectives

The objectives of the California Department of Health Services (CDHS) pandemic influenza program for laboratory diagnostic capacity are to:

- characterize and monitor interpandemic influenza activity year-round with continuous surveillance for the introduction of novel influenza strains;
- perform enhanced surveillance for other non-influenza, viral respiratory pathogens year-round (e.g., respiratory syncytial virus, parainfluenza virus, and adenovirus);
- once novel virus has been detected in California, monitor the level of novel influenza virus activity statewide, including antiviral resistance patterns;
- support special epidemiologic and clinical studies needed to evaluate phase-specific clinical interventions and containment measures;
- assist with the clinical management of individual patients by performing special studies, including distinguishing infections due to influenza from infections due to other respiratory viruses; and
- support individual case decisions surrounding isolation and quarantine.

2.3 Assumptions

- A comprehensive laboratory program that offers diagnostic testing for multiple respiratory agents is critical to monitoring for the introduction of a novel virus in California, as many respiratory agents can mimic the signs and symptoms of influenza.
- The CDHS Viral and Rickettsial Disease Laboratory (VRDL) will provide the necessary leadership and guidance to local public health laboratories.

- Building strong, statewide laboratory-based surveillance in the interpandemic phase, including strengthening of partnerships between CDHS VRDL and local public health, private, and commercial laboratories will enhance the ability to monitor for disease activity and ultimately strengthen control measures.
- During the earliest stages of a pandemic, public health, hospital, and clinical laboratories will receive a large and potentially overwhelming volume of samples.
- During a pandemic, laboratory surveillance data such as the confirmation of the presence or absence of a novel influenza virus in a given geographic area will guide implementation of control measures (e.g., travel restrictions, closure of schools and cancellation of public gatherings).
- During a pandemic, laboratory data identifying the emergence of new strains of novel virus will guide the implementation of vaccine strategies in target groups.
- During a pandemic, laboratory data identifying the presence or absence of antiviral drug resistance will guide the use of antiviral prophylaxis and treatment strategies in target groups.
- Once a pandemic is underway and human-to-human transmission is established, supplies of rapid antigens tests and reagents for immunofluorescence assays and polymerase chain reaction (PCR) will likely be depleted. At this stage, laboratory testing may be reserved for unusual or severe cases, special studies, or other specialized situations.

2.4 CDHS Pandemic Response Action Steps

2.4.1 WHO Phase 1 and Phase 2 - Interpandemic Period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals

- VRDL will develop and maintain laboratory testing algorithms, protocols and strategies for use by the state and local public health laboratories and the California Respiratory Laboratory Network (RLN) to perform both interpandemic influenza surveillance and detect the emergence of novel influenza strains. These protocols will include standard diagnostic tests (e.g., virus isolation, direct antigen testing by rapid antigen tests and PCR, and serologic testing) and support the role of the public health laboratory in diagnosing interpandemic influenza under routine circumstances and in outbreak situations.
- In coordination with the local public health laboratories, VRDL will develop and distribute recommended laboratory diagnostic guidelines for interpandemic influenza to all clinical settings where patients are likely to be managed (e.g., clinicians, clinical laboratories, and local public health laboratory and disease control staff), including the role of commercial rapid antigen test kits in routine and outbreak situations and guidance on how to obtain further testing at local and state public health laboratories, including specimen collection and transport protocols.

- VRDL will implement state of the art diagnostic testing algorithms for detecting and characterizing influenza, including testing for subtyping, strain-typing, immunity, and resistance.
- VRDL will transfer new technologies for influenza rapid testing (e.g., PCR and subtyping), to interested local public health laboratories, as appropriate. Local public health laboratories receiving this technology will participate in proficiency testing.
- VRDL and local public health laboratories will work to develop laboratory capacity (personnel, supplies, reagents, and training) at the local and state levels to perform year-round laboratory-based surveillance during the interpandemic period.
- VRDL and the California Association of Public Health Laboratory Directors (CAPHLD) will work to develop an inventory of current laboratory capacity in the state, identifying gaps in coverage and identifying recommended strategies to fill capacity gaps.
- VRDL and CAPHLD will estimate future laboratory capacity requirements under various pandemic scenarios and identify strategies for working toward enhancing future capacity.
- VRDL will develop a policy for storing and sharing selected isolates and specimens to support special clinical and epidemiologic studies with both local public health laboratories and the Centers for Disease Control and Prevention (CDC) and maintain an inventory of current storage capacities.

2.4.2 WHO Phase 3 and Phase 4 - Pandemic Alert Period: Human infection with no or very limited human-to-human transmission

- VRDL and local public health laboratories will encourage healthcare providers and clinical laboratories to submit specimens from suspected cases of human infection with novel influenza to a local or state public health laboratory for viral testing.
 - VRDL, in coordination with local public health laboratories, will develop and distribute guidelines to hospitals, healthcare providers, and clinical laboratories describing how to request testing for novel influenza virus.
 - VRDL, in coordination with local public health laboratories, will develop and distribute protocols to ensure that clinical laboratories notify their local public health laboratory of requests for testing for novel influenza virus.
 - VRDL will develop guidelines for specimen collection, handling, and shipping, and post them on the VRDL-Flu website (www.dhs.ca.gov/ps/dcdc/VRDL/html/FLU/fluintro.htm).
 - VRDL will adapt and distribute laboratory biosafety guidelines for handling and processing specimens or isolates of influenza A (H5N1) strains and post them on the VRDL-Flu website (www.dhs.ca.gov/ps/dcdc/VRDL/html/FLU/fluintro.htm).
- VRDL will develop and activate enhanced laboratory testing protocols in support of and in coordination with enhanced human surveillance protocols. VRDL will develop

capacity for subtype testing for influenza A (e.g., H5, H7) at either the local or state levels, as well as testing to identify other respiratory pathogens that present with influenza-like illness. VRDL will coordinate transporting to CDC any influenza A virus that cannot be subtyped.

- VRDL will provide detailed guidance to local public health laboratories on alternative diagnostic testing options, including rapid antigen detection, immunofluorescence assays, and PCR, including required biosafety levels.
- VRDL will develop contingency plans for possible nationwide supply and reagent shortages, including performing inventory of its own supplies and equipment and determining trigger points for ordering surge supplies. VRDL will prioritize reagent preparation for identifying the novel virus strain in preparation for phase 5-6 and distribute California- or CDC-prepared reagents and primers to local public health laboratories that are enrolled in the state's RLN, as available.
- VRDL will work to develop appropriate personnel capacity (including training) to support enhanced laboratory surveillance for influenza at the state and local levels. VRDL will internally evaluate the need for additional personnel surge capacity, including re-certification of non-traditional labor pool and redirection and hiring of additional laboratory employees.
- VRDL and the Microbial Diseases Laboratory (MDL) will work to develop contingency plans to ensure adequate laboratory capacity for diagnostic testing of bacterial agents and other pathogens associated with infections secondary to influenza.
- VRDL will institute surveillance for influenza-like illness among its own laboratory personnel working with novel influenza viruses, and develop protocols for clinical assessment and management of exposed laboratory personnel (both symptomatic and asymptomatic).
- CDHS will ensure at least one "BioSafety Level (BSL) -3 enhanced laboratory" exists within the State public health laboratory system.

2.4.3 WHO Phase 5 - Substantial Pandemic Risk: Larger clusters but still limited human-to-human transmission; sustained community transmission is possible

- VRDL will review and revise enhanced laboratory diagnostic protocols for influenza and other respiratory pathogens that may mimic influenza and distribute to local public health laboratories.
- VRDL will develop contingencies and protocols at the state and local levels for redirecting resources to influenza testing and for rationing influenza testing.
- VRDL will review and revise technical guidance and provide training to local public health laboratorians as needed.
- VRDL will delineate resources needed to maintain expanded critical laboratory testing capacity during a pandemic, including laboratory equipment and supplies, re-certification

of non-traditional labor pool, and redirection and hiring of additional laboratory employees.

- VRDL will maintain expanded diagnostic testing including antiviral resistance testing, neutralizing antibody assays to test for immunity to the novel virus, and egg-based or other alternative culture methods to isolate novel viruses that are difficult to grow by standard culture methods.
- VRDL will ensure capacity to perform/support special clinical and epidemiologic studies.

2.4.4 WHO Phase 6 - Pandemic Period: Increased and sustained transmission in the general population

- VRDL will review and enhance laboratory diagnostic capacity for novel strain virus, with particular attention to rationing laboratory testing, as needed.
- VRDL will continue other phase 5 activities as appropriate.

Appendix 3 - Healthcare Planning

3.1 Introduction

This appendix addresses the California Department of Health Services' (CDHS) role in coordinating optimal response by, and adequate maintenance of, the state's diverse healthcare delivery system during a pandemic influenza emergency. California's healthcare system is composed of private and public healthcare entities. Oversight and regulation of, and emergency planning for, this diverse healthcare system are shared between multiple divisions within CDHS and other state agencies including the Emergency Medical Services Authority (EMSA) and the Office of Statewide Health Planning and Development (OSHDP). Additionally, the Governor's Office of Emergency Services (OES) is the lead state agency for emergency management and coordinates with state agencies, including CDHS, to prepare for, mitigate, respond to, and recover from emergencies.

The increased demand for health care during an influenza pandemic will challenge existing healthcare resources in California to a level not been previously experienced. The "over-capacity" protocols in place at most hospitals are designed to accommodate a large number of patients over a short and limited period of time. A pandemic will require a health response sustained for a period of months or years. Planning for this kind of sustained response presents a unique challenge to hospitals and other healthcare entities, and will require a high level of collaboration and integration between all healthcare partners. CDHS must work collaboratively with local health departments (LHDs), emergency medical systems (EMS), healthcare facilities (HCFs), medical providers, regions, state agencies, and others to prepare to meet this demand.

3.2 Background

CDHS pandemic planning efforts build upon local, regional, and state planning efforts. Under the National Bioterrorism Hospital Preparedness Program funded by the Health Resources and Services Administration (HRSA), local entities have convened groups to develop plans to respond to a sudden and marked increased demand for patient care related to a bioterrorism event. As required by the HRSA cooperative agreement, the local planning groups include representatives from various healthcare partners including LHDs, hospitals, clinics, poison control centers, emergency medical services, and other stakeholders. These local planning groups must meet benchmarks to ensure sufficient patient care capacity in an emergency, including establishing a system that can provide triage, treatment, and initial stabilization, above the current daily staffed bed capacity, for pediatric and adult patients at 500 cases per million population (1:2000). This HRSA benchmark is a starting point for healthcare planning, but may be inadequate during a pandemic that lasts for an extended time and affects the entire state.

3.3 Objectives

The objectives of the CDHS pandemic influenza program for healthcare planning are to:

- maintain to the greatest extent possible the provision of healthcare services that are sufficient to meet the needs of all Californians during an influenza pandemic;
- maximize California's ability to respond to the healthcare needs of an influenza pandemic through effective planning at the state level; and

- collaborate with LHDs and healthcare providers to address the medical surge capacity and capability demands of an influenza pandemic.

3.4 Assumptions

- CDHS is the lead state agency for public health during a pandemic. OES is the lead state agency for overall coordination of emergency response. CDHS coordinates with EMSA in the state response to medical emergencies.
- LHDs are the lead entities for pandemic planning on a community level.
- Local pandemic healthcare planning should be coordinated by LHDs and include active participation from hospitals, EMS, clinics, private practice physicians, home-based care, long-term care facilities, and other healthcare partners.
- Local pandemic healthcare planning will build on local surge planning efforts undertaken through the HRSA cooperative agreement.
- The increased demand for health care during an influenza pandemic will severely challenge the capacity of the healthcare system in California.
- Capacity for medical mutual aid may be limited within California and between states and Baja California due to the widespread impact of an influenza pandemic.
- Medical surge capacity is “the ability to evaluate and care for a markedly increased volume of patients that challenges or exceeds normal operating capacity.” Medical surge capability is “the ability to manage patients requiring unusual or very specialized medical evaluation or care”¹ related to pandemic influenza.
- Local medical surge capacity planning must include cooperative strategies that use a variety of healthcare entities including hospitals, clinics, long-term care facilities, private practice physicians, and home-based care providers.
- A system of effective outpatient management may reduce the demand for inpatient care. Home-based treatment provided by families who are supported by primary care practitioners, public and home health agencies, or other health professionals will be an essential resource during a pandemic.
- The Governor’s authority to declare a state of emergency for California can enable CDHS to modify healthcare standards in order to meet the immediate needs for patient care related to the influenza pandemic emergency.
- To maximize healthcare resources and achieve the optimal benefit for the most people, traditional standards of care may need to be altered. “Sufficiency of care,” medical care that may not be of the same quality as that delivered under non-emergency conditions

¹ Medical Surge Capacity and Capability. The CNA Corporation, 2004.

but that is sufficient for need², may be the standard of care during an influenza pandemic.

- Hospitals will be expected to maximize their medical surge capacity. CDHS will grant permission to exceed licensed capacity under appropriate circumstances. However, when hospital capacity is exceeded, alternative treatment sites will be needed for patients who can be safely managed outside of the acute care setting and hospitals will be reserved for patients needing the most sophisticated level of care.
- Alternative treatment sites will be coordinated at the local level.
- Hospitals and other healthcare entities will experience staffing shortages throughout the duration of a pandemic and into the recovery period.
- Volunteers, retired healthcare professionals, and trained, unlicensed personnel may be used under specific emergency conditions to augment patient care in a variety of healthcare settings.
- Mass fatality care at all levels, including HCFs, county morgues, and mortuaries must plan for surge capacity and capability during an influenza pandemic.
- Exercising pandemic influenza plans is essential.
- Coordination and communication for pandemic healthcare planning must cross state lines and include the California - Baja California region.

3.5 Planning Principles

The planning activities described in this section are complex and extend across pandemic phases.

Pandemic healthcare planning is divided into the components listed below.

- **Facilities**, both existing/traditional and alternative treatment sites (e.g., temporary structures, reopened health facilities, school gymnasiums, armories, hotels and motels, convention centers), include physical structures, critical infrastructures such as plant operations and transportation, and the command systems to run them.
- **Equipment and Supplies** include equipment needed for patient care (e.g., beds, ventilators, heating/ventilating/air conditioning) and medical supplies such as pharmaceuticals, consumable medical equipment (e.g., intravenous sets [IVs], personal care supplies for patients, and personal protective equipment (PPE) for staff.
- **Personnel** includes maximizing the existing staffing resources and expanding staffing resources with alternative practitioners, volunteers, and newly recruited personnel.

² Surge Hospitals: Providing Safe Care in Emergencies. Joint Commission on Accreditation of Healthcare Organizations, 2006

- **Statutes, regulations, and policies** established by the state and federal governments to govern healthcare provision and practice may be modified or waived during an emergency.
- **Protocols, procedures, and guidelines** needed to manage patients during a pandemic in various settings include staffing plans, transfer procedures, infection control guidelines, clinical pathways and protocols for treating influenza patients, triage prior to entry into the HCF, and rationing scarce commodities like ventilators.
- **Training** is necessary for healthcare providers, families, volunteers, and newly recruited staff.
- **Coordination and communication** must occur within facilities, the local health jurisdiction, regionally, and statewide.

3.6 CDHS Pandemic Response Action Steps

3.6.1 WHO Phase 1 and Phase 2 - Interpandemic Period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals

Facilities

CDHS will:

- draft model emergency orders to ensure sufficient medical surge capacity;
- review, update, and if necessary, seek revised or expanded regulatory or statutory authority to ensure that hospitals and other HCFs complete emergency preparedness planning related to pandemic influenza;
- explore legal authority to require HCF emergency planning as a condition of licensure, including:
 - requiring hospitals to develop specific triggers (or thresholds) for canceling elective surgeries, opening beds previously placed in suspense, and using alternate space or temporary shelters to manage increased capacity demands;
 - requiring long-term care facilities to develop enhanced systems for infection control and plans for managing more acute patients, either emergency admissions or existing residents who are unable to be transferred to acute care hospitals due to lack of capacity;
- review existing local patient capacity surge plans developed with HRSA funding and direct the revision of these plans as needed;
- ensure local plans include appropriate triggers that guide the activation of local medical surge capacity and capability plans; and

- in conjunction with EMSA, assess and enhance existing hospital bed reporting systems for statewide reporting of medical surge capacity.

Equipment and Supplies

CDHS will:

- ensure that each local entity medical surge plan developed with HRSA funding includes a system to maintain a current inventory of essential healthcare items such as cots, ventilators, PPE, and pharmaceuticals.
- collaborate with LHDs to inventory essential healthcare items and supplies throughout the state.

Personnel

CDHS, in conjunction with the Department of Consumer Affairs (DCA), EMSA, and other professional licensing entities, will:

- review existing legal authority related to the use of healthcare volunteers and scope of practice regulations;
- determine the viability of expanding scope of practice for certain licensed healthcare professionals during an influenza pandemic, including:
 - paramedics;
 - emergency medical technicians;
 - nurses;
 - dentists;
 - veterinarians;
 - podiatrists;
 - pharmacists;
- determine mechanisms to permit unlicensed healthcare workers and volunteers to perform specific patient care procedures, including vaccinations and dispensing prophylactic medication during an influenza pandemic;
- ensure that local medical surge plans developed under HRSA funding include surge strategies to meet staffing needs; and
- develop and maintain a system to identify the skills of CDHS staff that are healthcare workers and develop a plan for deploying these staff during a pandemic.

CDHS in cooperation with EMSA, the California Service Corps (CSC), LHDs, and others, will:

- support the development of Medical Reserve Corps (MRC) in all counties and plans for their deployment;
- assist in developing guidelines for the use of MRC; and
- participate in developing an Emergency System for the Advanced Registration of Volunteer Health Professionals (ESAR-VHP) in California.

Communications

Communication is a critical aspect of all emergency planning and response. Priority must be given to ensuring timeliness and accuracy of communication by all programs involved in planning for and responding to pandemic influenza and all other public health emergencies. Procedures and protocols for incorporating regular communication actions will be included in each phase of pandemic influenza planning and response to facilitate sharing of information and messages with CDHS divisions, other response partners at the state and local level, and the public.

CDHS will ensure communications mechanisms, such as the California Health Alert Network (CAHAN) and the CDHS website, and disseminate pandemic influenza related information to LHDs and healthcare providers, including hospital-based infection control practitioners.

Mass Fatalities

CDHS will ensure that local medical surge capacity and capability plans developed with HRSA funding address the management of mass fatalities related to an influenza pandemic.

3.6.2 WHO Phase 3 and Phase 4 - Pandemic Alert Period: Human infection with no or very limited human-to-human transmission

Facilities

CDHS, in conjunction with medical professional organizations and academic stakeholders, will:

- issue recommendations for patient triage including:
 - prioritizing limited resources within the healthcare system;
 - assigning patients to specific treatment settings (e.g., medical center, clinic, long-term care, home care, alternative treatment sites); and
 - accelerating discharge of patients from one level of care to another;
- provide recommendations for the use of alternative treatment sites, including:
 - activation criteria;

- minimum requirements for size, power, air and heat, equipment, supplies and security;
 - staffing;
 - infection control;
 - liability;
 - memoranda of understanding;
 - best practices from other jurisdictions and states; and
- address identified barriers to the use of alternative treatment sites, including developing model emergency orders.

CDHS, in conjunction with the California Department of Food and Agriculture, will:

- assess the potential use of local fairgrounds for pandemic-related activities.

CDHS, in conjunction with EMSA, will:

- develop and test a statewide hospital capacity monitoring system to assess the medical surge capacity and capability of acute care hospitals.

Equipment and Supplies

CDHS will:

- collaborate with LHDs to complete the inventory of supplies and stockpile additional supplies;
- in conjunction with state, local, and private entities, analyze key pandemic supplies throughout the State to determine the supply capability and recommend actions to mitigate anticipated supply problems; and
- assess the feasibility of developing regional stockpiles for essential medical equipment and supplies and develop distribution plans for these materials.

Personnel

CDHS will:

- disseminate completed work products of phases 1–2 related to healthcare professional scope of practice requirements;
- advise LHDs and healthcare providers regarding pending emergency orders for modifying scope of practice requirements;

- exercise local pandemic plans in collaboration with HCFs and other providers, OES, the Governor's Office of Homeland Security (OHS), LHDs, regional and local coordinators, healthcare volunteers, and expanded practice professionals;
- collaborate with EMSA to develop call-up, activation, and deployment procedures and protocols for healthcare professionals who participate in an advanced registration system; and
- implement procedures for the identifying CDHS healthcare personnel.

Communication

CDHS will:

- convene regular conference calls with LHDs and other partners to discuss pandemic progress and scope, and to refine healthcare planning guidance as indicated; and
- use the CDHS web site, CAHAN, and other communication mechanisms to transmit pandemic related information for the public, healthcare delivery organizations, their employees, volunteer workers, and LHDs.

Mass Fatalities

CDHS, working with OES, DCA, the State Registrar of Vital Records, coroner representatives, and others, will:

- clarify jurisdictional authority and resolve issues concerning the large-scale management of mass fatalities related to an influenza pandemic;
- develop model emergency orders to facilitate mass body storage;
- issue recommendations for the definition of a medical examiner/coroner's case based on the case definition of infection with the pandemic influenza virus; and
- issue recommendations on mass fatality management for HCFs.

3.6.3 WHO Phase 5 - Substantial Pandemic Risk: Larger clusters but still limited human-to-human transmission; sustained community transmission is possible

Facilities

CDHS will:

- continue action items as described in previous phases; and
- monitor medical capacity reports from hospitals to prepare for effective management of resource requests.

Equipment and Supplies

CDHS will:

- continue and complete action items described in previous phases; and
- collaborate with LHDs to ensure the readiness of stockpiled supplies and distribution systems.

Personnel

CDHS will:

- continue and complete action items described in previous phases;
- train CDHS healthcare personnel for pandemic response; and
- test deployment protocols for CDHS healthcare personnel.

Communication

CDHS, in conjunction with EMSA, will:

- activate the Joint Emergency Operations Center (JEOC) to ensure readiness for surge response, focusing on communication regarding the status of the pandemic, and the coordination of healthcare personnel, facilities, equipment, and supplies.

CDHS will:

- continue action items described in previous phases.

3.6.5 WHO Phase 6 - Pandemic Period: Increased and sustained transmission in the general population

CDHS will:

- following the Governor's declaration of a state of emergency, activate emergency plans for personnel, supplies, alternative treatment facilities, and mass fatality management;
- in conjunction with EMSA, DCA, and OES, implement emergency orders and protocols related to healthcare providers licensure, scope of practice, staffing requirements, patient capacity, alternative treatment facilities, healthcare volunteers, and the management of mass fatality remains;
- through the JEOC, monitor and coordinate the following activities in response to local and regional resource requests transmitted through OES:
 - use and supply of additional personnel;

- use, requisitioning, and expansion of healthcare facilities, including alternative treatment sites and fatality management resources;
- use and supply of equipment, supplies, and pharmaceuticals; and
- use and supply of healthcare transportation resources.

3.7 WHO Postpandemic Period - Recovery

Pandemic influenza is anticipated to arrive in two to three waves over the course of several years, with a trough between the waves. These troughs – substantial decreases in new cases – offer opportunities for recovery similar to the return to the interpandemic phase that would occur after the cessation of the pandemic, and a chance to regroup, learn, and prepare for the next wave.

CDHS will:

- identify and disseminate best practices related to information dissemination, clinical management, infection control, coordination of patient management, etc.;
- compile reports of shortages to validate planning assumptions regarding critical supplies and resources;
- compile morbidity and mortality reports by treatment setting to understand how care may best be provided;
- evaluate use of volunteers, expanded scope, alternative treatment sites, etc.;
- adjust guidance for use of personnel, supplies, and facilities; and
- review and update guidance and recommendations issued during the previous phases in accordance with current evidence and available resources.

Attachment 3A - Planning Considerations for Healthcare Facilities (HCF)

This section is intended to assist hospitals and other HCFs to prepare for pandemic influenza. HCFs should review the activities outlined below and consider them when developing and evaluating their pandemic response plans.

3A.1 Assumptions

- Medical surge capacity is “the ability to evaluate and care for a markedly increased volume of patients that challenges or exceeds normal operating capacity.” Medical surge capability is “the ability to manage patients requiring unusual or very specialized medical evaluation or care.”³
- Healthcare planning for pandemic influenza builds on efforts initiated under the National Bioterrorism Hospital Preparedness Program funded by the Health Resources and Services Administration (HRSA).
- The increased demand for health care during an influenza pandemic will severely challenge the capacity of the healthcare system in California.
- Hospitals will be expected to maximize their medical surge capacity and capability. However, when hospital capacity is exceeded, alternative treatment sites will be needed for patients who can be safely managed outside of the acute care setting, and hospitals will be reserved for patients needing the most sophisticated level of care.
- The increase healthcare demands associated with pandemic influenza cannot be managed by HCFs alone. An effective pandemic response must include cooperative strategies that use a variety of healthcare entities including hospitals, clinics, long-term care facilities, private practice physicians, and home health care providers.
- A system of effective out-patient management may reduce the demand for inpatient care. Expanded clinic services and home health care provided by families who are supported by primary care practitioners, public and home health agencies, or other health professionals will be essential resources during a pandemic.
- Hospitals and other healthcare entities will experience staffing shortages throughout the duration of a pandemic and into the subsequent recovery period. Under specific emergency conditions, volunteers, retired healthcare professionals, and trained unlicensed personnel may be used to provide patient care in a variety of healthcare settings.
- Current resources for mass fatality care at all levels, including HCFs, county morgues, and mortuaries may be inadequate to meet the challenges posed by an influenza pandemic.
- To maximize healthcare resources and achieve the optimal benefit for the most people, traditional standards of care may need to be altered. “Sufficiency of Care,” medical care that may not be of the same quality as that delivered under non-emergency conditions

³ Medical Surge Capacity and Capability. The CNA Corporation, 2004.

but that is sufficient for need⁴, may be the standard of care during an influenza pandemic.

- The pandemic could last for months or years. Local pandemic planning groups and HCF internal committees should meet regularly to assess the effectiveness of their pandemic response and modify efforts as indicated.

3A.2 Decision-making and Coordination

Each HCF should:

- convene an internal pandemic influenza planning committee to develop/revise a pandemic preparedness plan for the facility that includes:
 - incident management protocols for a sustained continuity of hospital operations and patient care services;
 - specific pandemic influenza planning strategies that incorporate current state and federal guidance;
 - triggers for activating the HCF's internal pandemic emergency plan; and
 - assignment of authority and responsibility for pandemic planning and response within the facility;
- participate in community pandemic planning groups that include the LHD, the Medical Health Operational Area Coordinator, the Local Emergency Medical Services Agency (LEMSA), and representatives from other HCFs, including clinics, long-term care facilities, and home health agencies;
- discuss with partners listed above patient management strategies to preserve hospital capacity for patients needing the most sophisticated, including:
 - community education and communication (see Appendix 9);
 - public health outreach to promote self care (see Appendix 9);
 - expanded clinic use;
 - use of home health agencies and in-home health services to facilitate outpatient management;
 - collaboration with long-term care facilities to minimize hospital admissions of nursing home patients and maximize long-term care resources for managing stable, non-contagious hospital patients;

⁴ Surge Hospitals: Providing Safe Care in Emergencies. Joint Commission on Accreditation of Healthcare Organizations, 2006. , "Sufficiency of Care" is medical care that may not be of the same quality that is delivered under non-emergency conditions, but is sufficient for patient needs.

- collaboration among healthcare and community leaders on plans to operate, equip, staff, and transport patients to alternative treatment sites (e.g., shuttered hospitals, outpatient facilities, veterinary hospitals, non-medical facilities) for triage and/or management;
- coordinated memoranda of understanding (MOU) or other agreements for procuring and distributing resources and supplies within the jurisdiction; and
- liaison with local, regional, and state officials; volunteer groups; and community based-organizations to plan a surge response, identify potential healthcare volunteers, and exercise local, regional, and state plans.

3A.3 Legal/Ethical

The HCF's internal pandemic influenza planning committee should include representation from the facility's ethics/human subjects committee, infection control practitioners, emergency management committee, staffing director, administration, and physician leadership. The committee should review/develop policies on:

- requesting and obtaining emergency waivers to regulatory requirements (e.g., Health Insurance Portability and Accountability Act, Emergency Medical Treatment and Active Labor Act, staffing ratios, scope of practice restrictions);
- enforcing isolation and/or quarantine protocols;
- allocating limited resources and issues related to the "sufficiency of care";
- allocating vaccines and antivirals for both staff and patients;
- establishing temporary patient care areas and morgue space within the facility;
- using volunteer and newly recruited personnel;
- accelerating discharge to alternative treatment sites and/or home based care; and
- deferring elective procedures.

3A.4 Facilities

Each HCF should:

- review and revise high patient census protocols to prepare for the intensity and duration of patient influx during an influenza pandemic;
- review and revise high patient census protocols to prepare for increased demands for isolation capacity;
- develop plans for use of overflow space to triage, transfer/discharge, and treat patients, including using suspended beds, converting out-patient space to in-patient, and using

non-patient areas and obtaining permission from CDHS Licensing and Certification Division to use these spaces in an emergency; and

- identify strategies to minimize emergency department visits and in-patient admissions, including patient and public education, phone advice guidance, and treatment algorithms.

3A.5 Personnel

Each HCF should:

- identify critical staff roles including healthcare workers, housekeepers, dietary and laundry workers, plant operations, security, chaplains and mental health staff, and management, and develop plans to cover these critical roles;
- develop pandemic-specific triggers for implementing critical staffing procedures and emergency plans.
- develop work force preservation protocols to minimize absenteeism, which may include:
 - establishing a staff hotline with current information;
 - providing sick care services for children of hospital staff;
 - developing rosters of staff teams that allow for rotation and rest over the duration of the pandemic;
- develop and conduct in-service training staff on the facility's pandemic response plan;
- prepare to manage volunteer personnel, including:
 - granting emergency privileges;
 - establishing competency and monitoring staff performance for newly recruited and/or volunteer personnel;
 - assigning temporary personnel;
 - using retired and volunteer healthcare workers for some patient care roles;
 - using community volunteers for non-clinical roles such as transporting specimens, registration, and supply handling;
 - training volunteers;
- coordinate staffing plans with the community pandemic influenza planning group to avoid competing for personnel resources;

- develop just-in-time training and orientation modules for temporary and volunteer staff; and
- develop model MOUs for using temporary personnel.

3A.6 Supplies

Each HCF should:

- inventory critical supplies;
- determine usage levels and consider stockpiling critical supplies;
- develop MOUs with vendors for procuring additional supplies including:
 - masks;
 - gloves;
 - gowns;
 - beds/cots;
 - intravenous (IV) supplies;
 - portable high efficiency particulate air filters; and
 - ventilators;
- test systems for procuring and storing additional supplies and address stockpile rotation issues;
- repair durable equipment not currently in full working order on an expedited basis and shorten routine maintenance cycle;
- coordinate supply plans with the local pandemic planning group to avoid competing for supplies; and
- in conjunction with the local pandemic planning group, develop a community-wide plan for supplying/equipping alternative treatment sites.

3A.7 Excess mortality

Each HCF should:

- review current disaster plan for managing remains and temporary morgue overflow;
- modify plans to address potential need to manage contaminated remains for days; and
- consider MOUs for surge mortuary supplies (e.g., body bags, refrigerator trucks).

3A.8 Disease Surveillance (See also Appendix 1 and Attachment 1.A)

Each HCF should:

- review passive and active surveillance systems and protocols for influenza-like illness, and update as needed;
- train and drill staff on policies and procedures for disease identification, testing, and reporting;
- consider participating in CDHS Immunization Branch Sentinel Provider reporting program;
- establish priorities for laboratory procedures, including processing specimens; and
- assess communication systems to ensure receipt of alerts and bulletins from local, regional, and state infection control partners and internal dissemination of those alerts.

3A.9 Infection Control (See also Appendix 4 and Attachment 4.1)

Each HCF should:

- convene the infection control committee to review and revise infection control policies and plans relevant to the pandemic response, including:
 - patient triage systems;
 - containment strategies;
 - respiratory hygiene;
 - isolation;
 - cohorting;
 - workforce issues such as training, personal protective equipment (PPE), and guidelines for “fitness for duty” status;
 - cleaning equipment/environment;
- review and update staff training in infection control policies and procedures, including training for non-clinical hospital personnel such as housekeepers, admitting clerks, and other critical support staff;
- require demonstration of staff proficiency in critical infection control techniques;
- adopt aggressive “respiratory hygiene” programs in all patient and visitor waiting areas to include signs about respiratory etiquette, hand cleaning supplies, tissues, masks, and waste receptacles; consider requiring all coughing patients to don a mask;

- inventory respiratory isolation capacity and integrity of airborne infection isolation room systems; and
- develop strategies for expanding respiratory isolation capacity and cohorting infectious patients.

3A.10 Vaccine Program and Antiviral program (See also Appendices 6 and 7)

Each HCF should:

- review current vaccination program for pneumonia and influenza;
- develop policies and protocols to identify high-risk patients for vaccine/antiviral distribution;
- identify critical hospital personnel for vaccination and antiviral medication; and
- collaborate with LHD on allocation plan for vaccine and antivirals.

3A.11 Case Management and Treatment (See also Appendix 5)

Each HCF should:

- adopt any treatment guidelines distributed by CDC and CDHS;
- develop standard operating procedures to ensure rapid and consistent application of treatment guidelines;
- train medical staff on treatment priorities, allocating limited resources, and “sufficiency of care” standard;
- drill staff on patient management; and
- develop systems to timely distribute updated guidance to clinical staff and revise policies and standard operating procedures accordingly.

Appendix 4 – Infection Control in the Healthcare Setting

4.1 Introduction

This appendix addresses infection control measures and practices in the healthcare setting and provides guidance to healthcare facilities on managing a pandemic influenza outbreak. The infection control guidance in this appendix is based on current knowledge of the routes of influenza transmission, the pathogenesis of the influenza virus, and the effects of influenza control measures used during past pandemics and interpandemic periods. The specific characteristics of a novel pandemic virus remain unknown until the pandemic occurs. The California Department of Health Services (CDHS) will revise this document as needed to meet the changing dynamics of a pandemic.

The primary strategies for preventing pandemic influenza are the same as those for seasonal influenza: vaccination, early detection and treatment with effective antiviral medications, and the use of infection control measures to prevent transmission during patient care. However, when a pandemic begins, a vaccine may not yet be widely available and the supply of antiviral drugs may be limited. The ability to limit transmission in a healthcare setting will rely heavily on the appropriate and thorough application of infection control measures.

Given the uncertainty about the characteristics of a new pandemic strain, all aspects of preparedness planning for pandemic influenza must allow for flexibility and real-time decision-making that take new information into account as the situation unfolds. Healthcare facilities should be prepared to implement engineering and administrative controls, and use of personal protective equipment (PPE) to prevent all possible modes of transmission, including airborne. This level of preparedness includes having a respirator program in place; pre-designating which employees might be required to wear respiratory protection; and ensuring that potential respirator users have been medically cleared, have selected a suitable respirator model through individual fit testing, and have been trained in respirator use. In addition, adequate supplies of respirators and other PPE must be onsite and plans in place to acquire additional equipment on short notice.

4.2 Objectives

The CDHS objectives for infection control measures in the healthcare setting are to:

- limit transmission from infected patients to non-infected healthcare staff;
- limit transmission from infected patients to non-infected patients; and
- provide infection control guidance to healthcare facilities on managing pandemic influenza outbreaks.

4.3 Assumptions and Planning Principles

Healthcare facilities should use the following assumptions in planning to prevent and respond to influenza pandemic.

- Susceptibility to the pandemic influenza subtype will be universal prior to vaccination.

- Healthcare providers must be prepared to manage the surge of pandemic influenza patients presenting for care based on general predictions from the U.S. Department of Health and Human Services and based on current data of influenza outbreaks.
 - The clinical disease attack rate is estimated to be 30 percent of the population.
 - Fifty percent of ill persons will seek outpatient medical care.
 - Hospitalization will be required for a large number of those severely ill.
 - About 20 percent of working adults will be affected.
 - Illness rates will be the highest among school-aged children (approximately 40 percent) and decline with age.
 - An average of two secondary infections will occur per infected person.
 - The pandemic may last up to 18 months and several waves are likely.
 - Following the pandemic, the new viral subtype is likely to continue circulating and to contribute to seasonal influenza.
- People may be asymptomatic while infectious and the incubation period may be as little as two days, the same as with seasonal influenza.
 - Viral shedding will occur one-half to one day prior to the onset of illness.
 - Shedding will be the heaviest in the first two days after symptoms develop.
 - Children are typically heavy shedders in the first few days of illness (one day prior to onset of illness and two days after).
- Infection control needs will expand and change as an influenza pandemic evolves from the initial stages when a novel influenza strain is first identified in one or more persons to when a pandemic, with efficient human-to-human transmission, actually occurs. CDHS will review available data and scientific evidence, consult with local health officers (LHOs), review national recommendations, and revise and update guidance and recommendations as indicated.
- The modes of transmission of a novel virus influenza pandemic may vary from seasonal influenza outbreaks. Therefore, the California Division of Occupational Safety and Health (Cal/OHSA) in the Department of Industrial Relations, in collaboration with the Occupational Safety and Health Standards Board, could develop workplace standards applicable to the influenza pandemic, altering the recommendations in this appendix and designed to prevent transmission in California workplaces, particularly in the healthcare delivery system. Cal/OSHA may develop the workplace standards even if influenza transmission has not reached the pandemic phase, but presents a workplace hazard.
- Once the pandemic is underway and human-to-human transmission is established, infection control resources may be limited and strained. Healthcare providers must be

prepared to prioritize patient care, allocate scarce resources, and manage the patient surge. Planning should include anticipating and obtaining adequate supplies of personal protective equipment.

4.4 Modes of Influenza Transmission

Despite the prevalence of influenza year after year, most information on the modes of influenza transmission from person to person is indirect and largely obtained through observations during outbreaks in healthcare facilities and other settings (e.g., cruise ships, airplanes, schools and colleges); the amount of direct scientific information is very limited. However, the epidemiologic pattern observed is generally consistent with spread through close contact (i.e., exposure to large droplets, direct contact, or near-range exposure to aerosols). There is little evidence of airborne transmission over long distances or prolonged periods of time. The relative contributions and clinical importance of the different modes of influenza transmission are currently unknown.

For any novel or pandemic strain, the information on transmission and subsequent decision-making and recommendations for levels of personal protection and isolation precautions (i.e., droplet, contact, airborne) must be determined at the time of the pandemic, based upon the best available evidence at that time.

4.4.1 Droplet transmission

Droplet transmission involves contact of the conjunctivae¹ or mucous membranes of the nose or mouth of a susceptible person with large-particle droplets containing microorganisms generated from person who has a clinical disease or who is a carrier of the microorganism. Droplets are generated from the source person primarily during coughing, sneezing, or talking and during the performance of certain procedures such as suctioning and bronchoscopy. Transmission via large-particle droplets requires close contact between source and recipient because droplets do not remain suspended in the air and generally travel only short distances (about three feet) through the air. Because droplets do not remain suspended in the air, special air handling and ventilation are not required to prevent droplet transmission. Large droplets (particles up to 100 microns in size) are considered inhalable or “inspirable,” even if they may not remain airborne for a long period of time; this fact provides support for the use of respiratory protection when a healthcare worker is in the vicinity of a coughing or sneezing patient.

Based on epidemiologic patterns of disease transmission, large droplet transmission is probably a major route of influenza transmission. However, data directly demonstrating large droplet transmission of influenza in human outbreaks is indirect and limited.

4.4.2 Contact transmission

Direct-contact transmission involves skin-to-skin contact and physical transfer of microorganisms to a susceptible host from an infected or colonized person, such as occurs when healthcare personnel turn patients, bathe patients, or perform other patient-care activities that require physical contact. Direct-contact transmission also can occur between two patients (e.g., by hand contact), with one serving as the source of infectious microorganisms and the

¹ There is uncertainty about the role of conjunctivae transmission and therefore there is uncertainty about recommending face/eye protection other than the standard precautions for protection against splash and spray.

other as a susceptible host. Indirect-contact transmission involves contact of a susceptible host with a contaminated intermediate object, usually inanimate, in the patient's environment. Contact transmission of influenza may occur through either direct skin-to-skin contact or through indirect contact with virus in the environment and subsequent contact with mucous membranes (i.e., mouth, nose, or eyes).

4.4.3 Airborne transmission

Airborne transmission occurs by dissemination and subsequent inhalation of airborne droplet nuclei or particles in the respirable to inspirable size ranges which contain the infectious agent. Microorganisms carried in smaller-size particles may be dispersed over long distances by air currents and may be inhaled by susceptible individuals who have not had close contact with (or been in the same room with) the infectious individual. Organisms transmitted in this manner must be capable of sustaining infectivity, despite desiccation and environmental variation that generally limit survival in the airborne state. Preventing the spread of agents that are transmitted by the airborne route requires the use of special air handling and ventilation systems (e.g., negative-pressure rooms). The relative contribution of airborne transmission to influenza outbreaks is uncertain.

There are insufficient studies to determine whether influenza transmission can occur across long distances (e.g., through ventilation systems) or through prolonged residence in air. However, transmission may occur at shorter distances through inhalation of small-particle aerosols (droplet nuclei), particularly in shared air spaces with poor air circulation.

Some aerosol-generating procedures (e.g., endotracheal intubation, bronchoscopy) likely increase the potential for dissemination of droplet nuclei in the immediate vicinity of the patient. Therefore, healthcare personnel who perform aerosol-generating procedures on influenza patients should use additional precautions.

4.5 CDHS Pandemic Response Action Steps

4.5.1 WHO Phase 1 and Phase 2 - Interpandemic Period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals

- CDHS will provide influenza infection control recommendations, including respiratory protection measures, in consultation with the Centers for Disease Control and Prevention, the U.S. Occupational Health and Safety Administration (OSHA), California Division of Occupational Health and Safety (Cal/OSHA), and other state/ and federal organizations.
- CDHS will promote seasonal influenza education of the healthcare providers on the importance of respiratory etiquette and hand hygiene.
- CDHS Licensing and Certification (L&C) Division and Division of Communicable Disease Control (DCDC), in consultation with the Occupational Health Branch (OHB) will provide technical guidance to local health departments (LHDs), hospitals, clinics, and home health care agencies on influenza infection control practices and procedures, healthcare worker surveillance, outbreak identification reporting and response and other areas as needed.

- CDHS will provide current influenza information and updates on the website at www.dhs.ca.gov and through the California Health Alert Network (CAHAN).
- CDHS L&C and DCDC will collaborate with LHDs, healthcare providers, and healthcare organizations (e.g., California Hospital Association, California Medical Association, California Primary Care Association) to identify best practices and unique methods of infection control for influenza. These best practices will be communicated to healthcare providers through multiple channels including the CDHS website noted above.
- CDHS L&C will monitor the compliance of healthcare facilities with state and federal infection control regulations and statutes.

4.5.2 WHO Phase 3 and Phase 4 - Pandemic Alert Period: Human infection with no or very limited human-to-human transmission

- CDHS DCDC will recommend infection control guidelines for triaging patients entering the healthcare system (e.g., emergency departments, clinics, emergency medical services, physician offices), including spatial separation and masking (with a surgical or procedure mask) of potentially infected patients.
- CDHS L&C will collaborate with LHDs to ensure effective infection control measures and quality patient care in establishing alternate care site and in isolation and cohorting of influenza patients within rooms or areas of the facility.
- CDHS OHB, in consultation with Cal/OSHA, will provide technical expertise and recommendations for protecting the healthcare workers including recommendations for:
 - PPE for healthcare workers including respiratory protection;
 - alternate care and out-patient settings;
 - situations in which PPE is in short supply or unavailable due to patient demand and census; and
 - “fitness-to-work” guidelines for healthcare workers.
- DCDC, in consultation with OHB, will provide technical consultation and make technical recommendations for infection control practices and education of healthcare providers for the pandemic alert period, based upon existing clinical, laboratory, surveillance, and epidemiological data of the potential influenza pandemic, including:
 - instituting isolation and quarantine measures;
 - cohorting of infected patients;
 - protecting non-influenza hospitalized patients; and
 - training and educating healthcare workers.

4.5.3 WHO Phase 5 - Substantial Pandemic Risk: Larger clusters but still limited human-to-human transmission; sustained community transmission is possible and Phase 6 - Pandemic Period: Increased and sustained transmission in the general population

- DCDC will provide technical expertise and make recommendations for:
 - alternate healthcare provider infection control measures and practices when PPE is in short supply or unavailable;
 - hospital infection control measures and equipment when cohorting large numbers of patients in alternate care facilities; and
 - postmortem care.
- CDHS OHB, in consultation with Cal/OSHA, will provide technical expertise and recommendations for protecting the healthcare workers including:
 - protecting healthcare workers in alternate care and out-patient settings;
 - protecting healthcare workers when PPE is in short supply or unavailable due to patient demand and census; and
 - establishing “fitness-to-work” guidelines for healthcare workers.
- CDHS Division of Drinking Water and Environmental Management will make recommendations for effectively managing large quantities of infectious waste materials (medical and non-medical).
- CDHS L&C will monitor the demand and availability of infection control supplies and PPE to support healthcare provider delivery of safe and effective care. The Joint Emergency Operations Center (JEOC) will manage, procure, and allocate scarce infection control and PPE supplies to healthcare providers.

4.5.4 WHO Postpandemic Period

- DCDC will continue to monitor and assess surveillance, laboratory, epidemiologic, and clinical data in the postpandemic period.
- CDHS will, to the extent possible, evaluate the efficacy of infection control measures and practices during the pandemic, capturing best practices and lessons learned.

Attachment 4A - Recommendations for Infection Control in the Healthcare Setting

4A.1 Basic Infection Control Principles for Preventing the Spread of Influenza

The following infection control principles apply in any setting where persons with pandemic influenza might seek and receive healthcare services (e.g., hospitals, emergency departments, out-patient facilities, residential care facilities, homes.) Healthcare facilities should be adequately prepared to implement engineering or administrative controls, as well as personal protective equipment (PPE), to prevent all possible modes of transmission, including airborne. This level of preparedness includes the following: having a respirator program in place; pre-designating which employees might be required to wear respiratory protection; and ensuring that potential respirator users have been medically cleared, have selected a suitable respirator model through individual fit testing, and have been trained in respirator use. In addition, adequate supplies of respirators and other PPE must be onsite and plans in place to acquire additional equipment on short notice.

4A.2 Respiratory Hygiene and Cough Etiquette

Respiratory hygiene and cough etiquette are important strategies to contain respiratory viruses at the source and limit their spread from infectious patients. The elements of respiratory hygiene/cough etiquette include:

- educating healthcare workers, patients and visitors on the importance of containing respiratory secretions to prevent transmission of influenza; and
- posting signs in languages appropriate to the population served with instructions to:
 - immediately report symptoms of respiratory infection to the healthcare provider;
 - use source control measures (e.g., covering the mouth/nose with a tissue when coughing and disposing used tissues appropriately; applying a surgical or procedure mask on the coughing person as tolerated);
 - perform hand hygiene measures after contact with respiratory secretions; and
 - in common waiting areas, maintain to the extent practicable spatial separation (ideally at least three feet) between uninfected persons and person with respiratory infections.

4A.3 Other Basic Infection Control Measures

- Limit contact between infected and non-infected persons.
- Isolate infected persons (i.e., confine patients to a defined area as appropriate for the healthcare setting).
- Limit contact between nonessential personnel and other persons (e.g., visitors) and patients who are ill with pandemic influenza.
- Promote spatial separation in common areas (i.e., sit or stand as far away as possible - at least three feet) to limit contact between symptomatic and non-symptomatic persons.

4A.4 Infection Control in the Hospital Setting

4A.4.1 Detection of persons entering the facility who may have pandemic influenza

Infection control policies and procedures should include detection measures to limit exposure of others to infected individuals. Hospitals should post visual alerts in appropriate languages at the entrances of the hospital (e.g., emergency departments, clinics, lobby areas) to:

- instruct persons with respiratory symptoms to inform reception and healthcare personnel of their symptoms when they register for care or enter the facility;
- instruct persons with respiratory symptoms to practice respiratory hygiene/cough etiquette;
- discourage unnecessary visits to medical facilities; and
- educate patients, families, and visitors about infection control measures at home and in the community.

4A.4.2 Triage of Symptomatic Persons

During the peak of the pandemic, emergency departments and hospital-based clinics may be overwhelmed with patients seeking care. Facilities should consider implementing the following measures.

- **Patient Triage**
 - Establish a “triage officer” to manage patient flow, including deferring or re-directing patients who do not require emergency care, after performing a medical screening examination.
 - Designate a separate waiting area for patients with influenza-like symptoms. If this is not feasible, set up the waiting area(s) to allow spatial separation (three feet apart) from other patients.
- **Healthcare Worker Triage**
 - Implement a system to screen all healthcare personnel for influenza-like symptoms before coming on duty.
 - Determine “fitness-for-duty” criteria for employees to return to work, based on the clinical symptomology of the influenza pandemic utilizing recommendations developed by the California Department of Health Services (CDHS) Division of Communicable Disease Control (DCDC) and Occupational Health Branch (OHB) during the pandemic.

4A.4.3 Isolation Precautions and Patient Placement

For any novel or pandemic strain, the information on transmission and subsequent decision-making and recommendations for the levels of isolation precautions (i.e., droplet, contact,

airborne) and patient placement must be determined at the time of the pandemic, based upon the best available evidence at that time. All of the precautions discussed in this section (use of isolation rooms, N-95 respirators) are airborne precautions, which CDHS recommends for addressing a novel influenza until it becomes clear they are not needed. Planning considerations include the following.

- Hospitals should develop pre-event policies and procedures to limit admission of influenza patients to those with severe complications who cannot be cared for outside the hospital setting.
- Hospitals should place patients with suspected or laboratory-confirmed illness caused by a novel pandemic influenza virus into rooms with engineering controls (i.e., negative-pressure isolation rooms) or cohort these patients (see 4A.4 below) to minimize the risk of influenza transmission.
- During aerosol-generating procedures (i.e., bronchoscopy, endotracheal intubation), hospitals should use a negative-pressure isolation or procedure rooms to decrease the risk of transmission within the hospital.
- Hospitals should place patients with known or suspected pandemic influenza on airborne precautions (i.e., wearing an N-95 filtering facepiece respirator for entry into patient rooms, having the patient wear a surgical or procedure mask when transported outside the room) for a minimum of 14 days from the onset of symptoms.
- Immunocompromised patients may shed virus for longer periods and should be placed on airborne precautions for the duration of their illness.
- If patient symptoms include diarrhea, healthcare workers should also use contact precautions.
- If possible, hospitals should admit influenza patients to a single-patient room or to an area designated for cohorting of patients with influenza.

4A.4.4 Cohorting of Patients

During a pandemic, other respiratory viruses may be circulating concurrently in the community. To prevent cross-contamination of respiratory viruses, whenever possible, hospitals should assign only patients with confirmed pandemic influenza to the same room. Hospitals should:

- implement cohorting early in the course of a local outbreak to accommodate an anticipated surge of patients;
- designate units or areas of a facility for cohorting patients with pandemic influenza and preferably rooms with engineering controls (i.e., negative pressure isolation rooms);
- consult with the facility engineers when determining areas to cohort patients to address ventilation systems that are not shared with other areas or rooms;
- ensure that personnel assigned to the cohorted patient care units do not “float” or are otherwise assigned to other patient care areas;

- limit the number of personnel entering the cohorted areas to those necessary for patient care and support; and
- ensure that healthcare personnel adhere to infection control practices to prevent nosocomial transmission.

4A.4.5 Patient Transportation

- Hospitals should limit patient movement and transport outside of isolation areas to medically necessary purposes.
- Hospitals should use portable equipment (e.g., portable x-ray equipment) in the isolation area(s) and clean the equipment after each use, according to 4A.4.13 below.
- If transportation is necessary, patients should wear a surgical or procedure mask, if tolerated. If a patient cannot tolerate a surgical or procedure mask, apply the most practical measure to contain respiratory secretions such as placing a sheet or towel loosely over the nose/mouth or head.

4A.4.6 Visitors

Hospitals should:

- screen visitors for signs and symptoms of influenza before entry into the facility and exclude persons who are symptomatic;
- limit visitors to persons who are necessary for the patient's emotional well-being and care;
- consider having the patient wear a surgical or procedure mask, if tolerated, while the visitors are in the room;
- assume that family members accompanying the patient to the facility have been exposed to pandemic influenza and should wear surgical or procedure masks;
- educate visitors to pandemic influenza patients on the importance of wearing surgical or procedure masks, and using good hand hygiene and respiratory/cough etiquette; and
- post instructions on respiratory and cough etiquette and hand hygiene methods and make necessary supplies available.

4A.4.7 Hand Hygiene

Hand hygiene includes both hand washing with either plain or antimicrobial soap and water or use of an alcohol-based product (hand sanitizer including gels, rinses, foams and hand wipes) that does not require water.

- In the absence of visible soiling of the hands, approved alcohol-based products for hand disinfection are preferred over soap and water for superior immediate antimicrobial activity, reduced drying of the skin, and convenience.

- If hands are visibly soiled or contaminated with secretions, wash hands with soap (either non-antimicrobial or antimicrobial) and water.
- Healthcare personnel should perform hand hygiene:
 - after removing gloves;
 - between patient contacts; and
 - after removing PPE.

4A.4.8 Safe Work Practices

- The healthcare practitioner must perform safe and consistent work practices, and adhere to infection control policies and procedures to prevent transmission of pandemic influenza.
- Facility infection control policies and procedures should include education for employees on safe work practices including “hand awareness” (i.e., being alert to what you are touching and possible hand contamination).
- Healthcare personnel should:
 - practice good hand hygiene at all times;
 - avoid touching eyes, nose, mouth or exposed skin with contaminated hands (gloved or ungloved); and
 - remove contaminated gloves before touching surfaces (door knobs, light switches, keys, keyboards) and perform hand hygiene.

4A.4.9 Personal Protective Equipment (PPE)

Healthcare facility infection control policies and procedures should include measures to protect the healthcare worker from possible exposure and illness. Compliance of the healthcare provider to the measures is paramount to preventing transmission and infection and must be emphasized during provider education, monitoring, and follow up. Hospitals should consult current Cal/OSHA requirements pertaining to PPE, and also note that these requirements may change as a new standard addressing aerosol transmissible infectious diseases is promulgated.

4A.4.9.1 Gloves

Gloves made of latex, nitrile, vinyl or other synthetic materials are appropriate. However, if possible, latex-free gloves should be available for all healthcare workers in order to prevent the development of latex allergies. Healthcare workers should:

- wear a single pair of gloves for contact with blood and body fluids and during any hand contact with respiratory secretions (e.g., providing oral care, handling soiled tissues);
- ensure gloves fit comfortably;

- remove and dispose of gloves after each patient use; do not wash gloves for reuse;
- perform hand hygiene after removal of gloves;
- use other barriers (e.g., disposable paper towels, paper napkins) when there is only limited contact with a patient's respiratory secretions; and
- emphasize hand hygiene and hand awareness in patients.

Hospital infection control policies should address the prioritization of gloves when they are in short supply. Prioritization could include reserving the gloves for situations in which extensive patient or environmental contact with blood and body fluids is likely, such as during suctioning.

4A.4.9.2 Respiratory Protection

The relative roles of droplet versus small-particle airborne transmission of influenza remain uncertain. As long as there is uncertainty, the selection of respiratory protection for pandemic influenza must be assessed on a continual basis, using available evidence on the specific characteristics of the pandemic strain - virulence, transmissibility, and clinical manifestation.

Until the uncertainty has been resolved, healthcare workers should use, at a minimum, an N-95 filtering facepiece respirator when caring for a suspected or confirmed pandemic influenza patient. This respirator use should be in accordance with a respiratory protection program as specified by Cal/OSHA regulations, including medical evaluation, training and fit-testing. Facilities should be prepared by anticipating and ordering adequate supplies and by medically clearing, fit-testing, and training potential respirator users in advance.

Aerosol-generating procedures (e.g., bronchoscopy, intubation) create a higher concentration of pathogen-containing aerosol. Therefore, a higher level of respiratory protection than an N-95 filtering facepiece respirator, such as Powered Air Purifying Respirators (PAPR) with N, P, or R-100 cartridges should be used when it does not interfere with the performance of these procedures.

Aerosol-generating procedures should be conducted in an isolation room whenever possible.

Hospital infection control policies should address the prioritization of respirators when they are in short supply. Prioritization could include utilizing the respirators when in patient rooms, transporting patients, when in close proximity (three feet or less) of the patient and when there is a higher likelihood of exposure or aerosolization such as during bronchoscopy or intubation.

The CDHS DCDC, in consultation with OHB and Cal/OSHA, will provide timely expert technical consultation and make technical recommendations for the appropriate respiratory protection measures and equipment for the pandemic influenza based upon existing clinical, laboratory, surveillance, and epidemiologic data of the potential influenza pandemic, providing optimal protection for the healthcare worker.

4A.4.9.3 Gowns

- Most routine patient interactions do not necessitate the use of gowns.

- Healthcare personnel should wear a gown if soiling of personal clothes or uniform with a patient's blood or body fluids, including respiratory secretions is anticipated, for example:
 - during procedures that may generate increased small-particle aerosols of respiratory secretions (e.g., endotracheal intubation and bronchoscopy);
 - during procedures or activities involving holding the patient close (e.g., restraining a pediatric patient); and
 - during other patient care activities in which there is a likelihood of contact or exposure (changing linens, ambulating a patient).
- Healthcare personnel may use a disposable gown of synthetic fiber or cloth; the gown must fit the wearer as to fully cover the area to be protected.
- Healthcare personnel should wear the gown only one time and discard it into a laundry or waste receptacle.
- Healthcare personnel should perform hand hygiene after removing the gown.
- Healthcare facility infection control policies must include proper donning and doffing procedures, including hand hygiene measures.
- Hospital infection control policy should address the prioritization of gowns when they are in short supply and designate alternate coverings (e.g., patient gowns.) Infection control policies should clearly describe situations in which gowns are needed.

4A.4.9.4 Eye Protection/Goggles

Droplet transmission to the conjunctivae may be possible when a susceptible person is exposed to large-particle droplets generated from a person who has a clinical disease or is a carrier of the microorganism. If sprays or splatter of infectious material is likely, goggles or a face shield should be worn (e.g., when within three feet of a coughing/sneezing influenza patient).

4A.4.10 Disposal of Solid Waste

Standard precautions for contact with blood and body fluids (i.e., gloves) are required for biohazardous waste; there are no special precautions that are recommended for the disposal of respiratory secretions. Support personnel should be educated on proper PPE and procedures for handling waste materials.

4A.4.11 Linen and Laundry

Healthcare facilities should use standard precautions for contact with blood and body fluids (i.e., gloves) for the handling of linen and laundry.

4A.4.12 Dishes and Eating Utensils

Standard precautions for contact with blood and body fluids (i.e., gloves) are recommended for handling dishes and eating utensils used by a patient with known or possible pandemic

influenza. Infection control policies and procedures must address proper cleaning and use. Disposable products are not required.

4A.4.13 Patient Care Equipment

Follow standard practices for handling and reprocessing used patient care equipment including medical devices.

- Hospital personnel should wear gloves when handling and transporting contaminated patient care equipment
- Hospital personnel should decontaminate patient care equipment with an EPA-approved hospital disinfectant before removing it from the patient's room and clean, disinfect or sterilize re-usable patient care equipment as appropriate.
- Hospital personnel should decontaminate external surfaces of portable equipment used to perform x-rays and other procedures in the patient's room with an EPA-approved hospital disinfectant upon removal of the equipment from the patient's room.

4A.4.14 Environmental Cleaning and Disinfection

Cleaning and disinfecting environmental surfaces are important routine infection control measures in healthcare facilities. In addition to routine environmental decontamination, healthcare personnel should perform more frequent disinfection of commonly touched surfaces in patient occupied rooms and common areas. Follow facility procedures for post-discharge disinfection of an isolation room.

4A.4.15 Postmortem Care

Healthcare facilities should follow standard facility practices for the care of the deceased. These practices should include standard precautions for contact with blood and body fluids (i.e., gloves).

If autopsy or procedures are performed on a deceased person with suspected or confirmed influenza and the procedures involve generating higher concentration of aerosols (e.g., cutting through bone), a powered air purifying respirator (PAPR) with N, P, or R-100 cartridge should be worn.

4A.4.15 Laboratory Specimens and Practices

Healthcare personnel should follow standard facility and laboratory practices for the collecting, handling, and processing laboratory specimens.

Appendix 5 – Case Management

5.1 Introduction

The management of influenza is based primarily on sound clinical assessment and management of individual patients as well as an assessment of locally available resources such as rapid diagnostics, antiviral drugs and vaccines, and hospital beds.

Healthcare providers play an essential role in detecting an initial case of novel or pandemic influenza in a community. Early identification of cases through heightened clinical awareness of disease and swift action for isolation and initiation of treatment can benefit the individual patient and may slow the spread of influenza within the community. Rapid diagnosis and intervention with clinical care can potentially avert severe complications.

5.2 Objectives

The objectives of the California Department of Health Services' (CDHS) pandemic influenza program for case investigation and treatment are to ensure:

- early identification and proper management of cases to help slow the spread of disease in the pandemic alert phases;
- appropriate identification and triage of cases once the pandemic is underway; and
- regular education and updates of healthcare providers on recommended practices and protocols pertaining to novel and pandemic influenza.

5.3 Assumptions and Planning Principles

- Because specific data are not available in advance, planning assumptions regarding the clinical and epidemiologic profile of pandemic influenza viruses are based on inference and expert opinion drawn from previous interpandemic and pandemic influenza viruses.
- Neither the clinical characteristics of a novel or pandemic influenza virus strain nor the groups at highest risk can be defined beforehand. Thus, risk groups for severe and fatal infections can differ significantly from those of interpandemic influenza strains.
- Susceptibility to the pandemic influenza subtype or novel influenza virus strain will be universal prior to vaccination.
- The incubation period for seasonal human influenza averages two days. CDHS assumes this would approximate the incubation period for a novel virus strain that is transmitted between people by respiratory secretions.
 - People may be asymptomatic while infectious.
 - Viral shedding will occur one-half to one day prior to the onset of illness.
 - Shedding will be the heaviest in the first two days after symptoms develop.

- Children are typically heavy shedders in the first few days of illness (one day prior to onset of illness and two days after).
- Once the pandemic is underway and human-to-human transmission is established, infection control resources may be limited and strained. Healthcare providers must be prepared to prioritize patient care, allocate scarce resources, and manage the patient surge. Planning should include anticipating and obtaining adequate supplies of personal protective equipment.

5.4 CDHS Pandemic Response Action Steps

5.4.1 WHO Phase 1 and Phase 2 - Interpandemic Period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals

- The CDHS Division of Communicable Disease Control (DCDC) with advice from the CDHS Joint Advisory Committee on Public Health Preparedness (JAC) will update and distribute California-specific guidelines for controlling interpandemic influenza in healthcare and other congregate settings at the start of the respiratory season. Guidelines will include relevant excerpts from federal guidelines on vaccination, prophylaxis, and treatment. CDHS Licensing & Certification (L&C) Division will work with the Department of Social Services, the Department of Mental Health, and local health departments (LHDs) to distribute guidelines to healthcare facilities and individual practitioners.
- Based on Centers for Disease Control and Prevention (CDC) guidance, and in coordination with JAC and LHDs, CDHS will develop and distribute protocols on case management and laboratory diagnostics to LHDs. CDHS will work with LHDs to distribute or make protocols available to settings where cases (and their contacts) might be diagnosed.
- CDHS will work with LHDs to ensure that clinicians and laboratory scientists know how to access the most current recommendations for novel influenza case identification, management, and laboratory testing.

5.4.2 WHO Phase 3 and Phase 4 - Pandemic Alert Period: Human infection with no or very limited human-to-human transmission

- In coordination with CDC, CDHS will develop case management protocols to ensure that suspect human cases of novel influenza infection are promptly identified, isolated, and source(s) of exposure (animal vs. human) determined. Case management protocols directed to clinicians will address:
 - screening criteria (clinical and epidemiologic including travel and occupation);
 - notification procedures to local health authorities;
 - case management (infection control precautions, specimen collection and testing, appropriate evaluation of alternative diagnoses, nationally recommended management and treatment protocols); and

- identification of potentially exposed controls, should contact tracing be recommended.
- CDHS will distribute revised protocols on case management and laboratory diagnostics to LHDs and will work with LHDs to ensure protocols are available to clinicians in settings where cases (and their contacts) might be diagnosed.
- CDHS, in coordination with CDC, will develop and distribute guidance on managing patients who test negative for novel influenza virus, addressing the potential for false negative findings and the clinical and epidemiologic criteria that would warrant continued suspicion.
- CDHS, in coordination with CDC and LHDs, will revise and distribute other virus transmission prevention and control guidelines from phases 1-2 to reflect the circumstances of phases 3-4.
- CDHS and LHDs will continue to remind clinicians and laboratory scientists on how to access the most up-to-date recommendations for novel influenza case identification, management, and laboratory testing.
- CDHS, in coordination with CDC guidelines, will distribute revised guidance on vaccination, prophylaxis, and treatment recommendations based on most current national and state recommendations, including a prioritized list of treatment and prophylaxis priority recipients and will work with LHDs to ensure the revised guidance is made available to healthcare practitioners.
- If isolated cases emerge, CDHS will coordinate access to antiviral drugs, and as available, vaccine.

5.4.3 WHO Phase 5 - Substantial Pandemic Risk: Larger clusters but still limited human-to-human transmission; sustained community transmission is possible

- CDHS, in coordination with CDC guidance and LHDs, will revise and distribute protocols and guidelines from phases 3-4 to reflect the circumstances of phase 5, as needed.
- CDHS will coordinate access to vaccines, antiviral drugs, and other medications needed to mitigate and manage secondary infections.

5.4.4 WHO Phase 6 - Pandemic Period: Increased and sustained transmission in the general population

- CDHS, in coordination with CDC guidance, will revise case management and notification protocols that address the changing probability of disease (in pandemic alert phases, the likelihood that a patient will have novel virus infection is low; in later pandemic phases, the likelihood that a patient will have novel virus infection is higher). Protocols will address:
 - screening criteria (clinical and epidemiologic criteria);

- notification procedures to local health authorities (e.g., designate which subset of cases should be reported such as those that are severe or have unusual clinical manifestations); and
 - case management (e.g., infection control precautions, specimen collection and testing including prioritization if needed, appropriate evaluation of alternative diagnoses, nationally recommended treatment protocols).
- CDHS will distribute revised protocols on case management and laboratory diagnostics to LHDs and will work with LHDs to ensure that protocols are available to clinicians in settings where cases (and their contacts) might be diagnosed.
- CDHS, in coordination with CDC guidelines, will revise and distribute guidelines on the use of antiviral drugs for prophylaxis and treatment (addressing priority groups), on the use of vaccine if it is available (addressing priority groups); and on where laboratory testing can be done and by whom.
- CDHS and LHDs will continue to remind clinicians and laboratory scientists how to access the most up-to-date recommendations for novel influenza case identification, management, and laboratory testing.
- CDHS will coordinate access to vaccines, antiviral drugs, and other medications needed to manage secondary infections.

Appendix 6 – Pandemic Influenza Vaccine Program

6.1 Introduction

The United States has used influenza vaccines for more than 50 years and vaccines are the primary method for preventing influenza and its complications. Annual influenza vaccine development requires input from international organizations, advisory committees, the U.S. Department of Health and Human Services (HHS), and licensed vaccine manufacturers. This multi-step process typically takes nearly a year of work.

The amount of vaccine that can be produced in time to be used in an influenza season is a function of the capacity of the industrial manufacturing base and the growth characteristics of the viruses selected and used to produce the vaccine. In the event of a pandemic, increased domestic influenza vaccine production capacity would enhance the supply of vaccine using current production techniques.

6.2 Objectives

The objectives of the California Department of Health Services' (CDHS) Pandemic Influenza Vaccination Program are to:

- allocate, distribute, and coordinate administration of pandemic influenza vaccine as rapidly, efficiently, and equitably as possible to the appropriate target groups and populations; and
- monitor the safety and effectiveness of the California Pandemic Influenza Vaccination Program.

6.3 Assumptions and Planning Principles

6.3.1 Vaccine Delivery and Administration

- With assistance from the Emergency Preparedness Office's (EPO) Emergency Pharmaceutical Services Unit (EPSU), CDHS Immunization Branch (IZB) will be responsible for allocating vaccine to local health departments (LHDs), and will coordinate with the EPSU regarding distributing vaccine to LHDs.
- Vaccine delivery is less dependent on pandemic stage and will be based on vaccine availability, Centers for Disease Control and Prevention (CDC) recommendations, and CDHS prioritization.
- It may be more than six months after the novel virus is identified before vaccine is available for distribution.
- Two U.S. vaccine manufactures and others outside of the United States have produced H5N1 influenza vaccine and are currently conducting clinical trials. No vaccine or vaccine production method has any acknowledged superiority, nor have any manufacturers completed clinical trials.

- Two doses of vaccine administered at a minimum of four weeks apart will likely be required to develop maximal immunity to the novel virus. Availability of further data on safety and immunogenicity of a novel virus vaccine after one versus two doses will depend on ongoing human clinical trials.
- The federal government will purchase pandemic vaccine produced during the first few months (anticipated 3-6 million doses per week) and distribute it to states. State public health agencies will control the vaccine. This vaccine supply will be used to vaccinate priority groups determined by CDC guidelines, the Division of Communicable Disease Control (DCDC) Pandemic Influenza Work Group (PIWG), and the CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization Strategies¹ (see Attachment 6A).
- Once vaccine is available, it will take several months to produce an adequate supply of vaccine for the U. S. population. When first available, the federal government will distribute limited supplies of vaccine to states on a pro-rated basis. California comprises approximately 12 percent of the U.S. population, and can expect to receive 360,000 - 720,000 doses per week. Vaccine supply may eventually be augmented by additional manufacturers. New cell culture methods to increase vaccine production capacity are still early in the development phase and are several years away from being approved.
- The vaccine may be administered and distributed under “Investigational New Drug” (IND) protocols, requiring informed consent before administration and monitoring for possible adverse events after administration. Alternatively, vaccine may be administered under the U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA). EUA procedures minimize the administrative burden and may be preferable to IND protocols to facilitate streamlined and efficient administration of vaccine.
- The necessary legal authority for implementing potentially extraordinary measures to distribute vaccine (e.g., allowing non-licensed volunteers to administer vaccine²) and secure distribution sites under emergency conditions should be in place before a pandemic occurs
- Early, coordinated collaboration with tribal entities, bordering jurisdictions including states and Mexico, and federal authorities, on implementing vaccine distribution plans will be critical.

¹ A subgroup of the CDHS Joint Advisory Committee on Public Health Preparedness (JAC).

² California law governs who may administer a vaccine. These include physicians and surgeons (Health and Safety Code, section 1316.5), registered nurses (Business and Professions Code [BPC] section 2725 (b)(3)), physicians’ assistants (BPC section 3502.1), pharmacists (BPC section 4052), and medical assistants under authorization and supervision of a licensed physician and surgeon or podiatrist (BPC section 2069). If the practitioner is operating under a particular practice guideline or protocol (e.g., if a mass vaccination clinic was established), the licensed practitioner could delegate authority to screen/assess patient need for vaccination to a registered nurse, physician assistant, medical student, or resident. Restriction of these codes to allow non-licensed practitioners to administer vaccine is only rescindable by executive order of the Governor during a state of emergency.

6.3.2 Monitoring and Evaluation of Vaccine Coverage

- With support from CDHS, LHDs will have the primary responsibility for monitoring and evaluation activities.
- CDHS will establish a database to track vaccine distribution and administration. This database will include summary information required for vaccine tracking (e.g., lot number, clinic dates, etc.). If an electronic system for vaccine tracking is not feasible for LHDs, a back-up paper system will be used. The paper system will document the same variables as the electronic system.
- LHDs will have the primary responsibility for data entry. LHDs will transfer data to the CDHS IZB for summary analysis and interpretation.

6.3.3 Tracking for Adverse Vaccine Reactions

- CDHS will use the Vaccine Adverse Event Reporting System (VAERS), jointly coordinated by the FDA and CDC, to track adverse vaccine reactions. Healthcare providers, patients, and vaccine manufacturers will report serious adverse events on paper forms, by telephone, or electronically.
- CDHS, in conjunction with LHDs, will analyze VAERS and any other reports of serious adverse events to determine whether such events are reported more frequently than expected. CDHS will analyze signals of potential vaccine-associated events for biologic plausibility and may conduct specific epidemiologic studies to further assess possible causation.
- CDHS may supplement VAERS with additional surveillance and studies (e.g., active surveillance for adverse events in a sample of vaccines by telephone interviews or self-report diary cards).

6.3.4 Prioritization Strategies for Limited Vaccine

- Young, healthy adults were at high risk of morbidity and mortality in the 1918 influenza pandemic. Very young persons, elderly adults, and persons with underlying disease are at high risk of complications during seasonal influenza outbreaks. Specific morbidity and mortality rates must be determined during the pandemic.
- Vaccination strategies must be flexible and responsive to vaccine supply and the epidemiology of the pandemic. Epidemiologic investigations performed early in the pandemic will be important to help guide decision-making, for example, to determine the groups who are at highest risk for adverse health outcomes and the age-specific case-fatality rate.
- CDHS will weigh programmatic feasibility when implementing priorities. For example, as vaccine supplies expand and after vaccination of highest-priority target groups, it may be most feasible to vaccinate entire families or to provide vaccine by geographical area in mass clinics rather than further subdividing the population by priority.

- Vaccinating priority groups will likely be most efficient if the vaccination is given at the worksite (e.g., hospitals, fire stations, police stations). Prioritization strategies and implementation options for distribution of limited vaccine are included in Attachment 6A.
- CDHS will use risk communication strategies to convey information and justification on the selection of priority groups (see Appendix 9).

6.3.5 Pneumococcal Vaccine

- Increasing interpandemic pneumococcal vaccine coverage is more feasible than implementing pneumococcal vaccination as an additional intervention during a pandemic.
- Improving pneumococcal vaccination coverage during the interpandemic period will decrease demand when a pandemic occurs and decrease the risk of a pneumococcal vaccine shortage.
- Consistent with current practice, private healthcare providers, home health agencies, visiting nurse associations, LHDs, and others will distribute and administer pneumococcal vaccine.

6.4 CDHS Pandemic Response Action Steps

6.4.1 WHO Phase 1 and Phase 2 - Interpandemic Period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals

No or limited supplies of pandemic vaccine are available. Some vaccine may be available in the private sector, the Strategic National Stockpile (SNS), and/or possibly a CDHS stockpile.

- CDHS will promote seasonal influenza vaccination in traditional high-risk groups, particularly subgroups in which coverage levels are low (e.g., minorities and persons under age 65 years with chronic medical conditions). Increasing routine, annual vaccination coverage levels in these groups will facilitate access to these populations when a pandemic occurs. However, routine vaccination against the seasonal influenza vaccine strains is unlikely to protect against novel strains that emerge in a pandemic.
- CDHS will monitor seasonal vaccination coverage rates in traditional high-risk groups through annual population-based surveys.
- CDHS will promote pneumococcal vaccination coverage to reduce the incidence and severity of secondary bacterial pneumonia in traditional high-risk groups.
- CDHS will promote seasonal influenza vaccination coverage rates among healthcare workers.
- CDHS will use the CDC Vaccine Information Statement (VIS) that details the risks and benefits of the vaccine in English and will translate the VIS into commonly used languages in California.

- CDHS will develop and distribute informational materials to LHDs and healthcare providers (see Appendix 9).
- CDHS will encourage LHDs to exercise their mass vaccination plans.
- CDHS will develop, test, and implement a data management system to track influenza vaccine supply, distribution, and administration. CDHS anticipates using the CDC Countermeasures Response Administration (CRS) system.
- CDHS will communicate, and when appropriate, coordinate vaccine activities with Baja California.

6.4.2 WHO Phase 3 and Phase 4 - Pandemic Alert Period: Human infection with no or very limited human-to-human transmission

No or limited supplies of pandemic vaccine are available.

- CDHS will communicate regularly with CDC, vaccine manufacturers, and distributors to obtain updates on plans for vaccine production and distribution.
- CDHS will convene regular meetings with the DCDC PIWG and the CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization Strategies to determine prioritization strategies for vaccination when supplies are limited, and to guide LHDs in distributing and prioritizing within their jurisdictions. These recommendations will consider CDC guidelines; target populations, including those at highest risk for complications from influenza; and groups critical to maintaining health, social, government, and emergency response services (see Attachment 6A).
 - This panel will meet bimonthly to review and update recommendations based on vaccine supply and global surveillance and epidemiologic data on characteristics of the novel virus.
 - In conjunction with the panel, CDHS IZB will determine the approximate number of high-risk and priority individuals needing vaccination during a pandemic, using CDC and California Department of Finance population data.
 - CDHS will prioritize groups for vaccination in the following situations:
 - severe vaccine shortages;
 - moderate vaccine shortages; and
 - no vaccine shortages.
 - CDHS IZB will develop, maintain, and regularly update a database with estimated numbers of priority groups by jurisdiction.
- CDHS will coordinate with EPO EPSU to develop protocols for vaccine delivery including:

- preparing delivery, storage, and distribution plans with LHDs;
- coordinating vaccine delivery, security, and receipt, including whether vaccine is delivered by:
 - EPSU-arranged transportation;
 - vendors via a centralized CDC distribution system; or
 - manufacturers;
- determining whether to distribute vaccine to the public health sector (likely in the initial phase), the private sector, or a combination of the two;
- delivering, storing, securing, and distributing vaccine during a pandemic in the following situations:
 - severe vaccine shortages;
 - moderate vaccine shortages; and
 - no vaccine shortages;
- establishing and confirming storage sites for vaccine from SNS vendors and manufacturers at existing secure vaccine storage depots;
- determining allocation of vaccine to LHDs based on population and priority group strategies;
- coordinating with EPO to arrange secure delivery of vaccine from CDHS storage facilities to LHDs;
- providing LHDs with updated protocols for receiving, storing, securing, and administering vaccine, including encouraging identification of mass vaccination clinic sites, formation of memoranda of understandings (MOUs) with those sites, and ensuring adequate security of clinic sites and storage facilities;
- coordinating with EPO and LHDs to assess the local availability of vaccination supplies (including syringes, gloves, bandages, gauze, first aid supplies, biohazard containers, emergency kits to manage anaphylaxis, etc.);
- encouraging LHDs to coordinate with the Office of Emergency Services (OES) Operational Area Medical Health Operational Area Coordinator (MHOAC), Regional Emergency Operations Center, Regional Disaster Medical Health Coordinator or Specialist (RDMHC/S), and the Joint Emergency Operations Center (JEOC) to assess local surge capacity to staff mass vaccination clinics, and develop contingency plans for requests by LHDs for additional trained personnel;
- exercising the risk communication section of the CDHS SNS Plan in conjunction with overall EPSU planning; and

- exercising vaccine distribution plans at least annually.
- CDHS will review LHD plans for mass vaccination of the public once sufficient vaccine is available, and provide support and guidance as needed. CDHS will develop and distribute to LHDs mass vaccination clinic guidelines modified from CDC guidelines. The guidelines will include information on:
 - identifying mass vaccination clinic sites;
 - determining clinic staffing needs;
 - preparing duty statements for clinic staff;
 - developing protocols for vaccine storage, handling, and security;
 - supplying vaccination clinics;
 - developing clinic flow guidelines; and
 - risk communications and public information.
- CDHS will test the data management system for tracking vaccine supply, distribution, security, and administration and resolve problems to assure readiness for use in a pandemic.
- CDHS will ensure that appropriate legal authorities are in place for implementing major elements of the proposed distribution plan, such as:
 - implementing mandatory vaccination of groups determined by state public health officials as essential for public safety;
 - allowing non-licensed volunteers to administer vaccine; and
 - ensuring liability coverage for non-licensed volunteers providing medical services or administering vaccine.
- CDHS will ensure that contingency plans have been considered for emergency distribution of unlicensed vaccine using IND or EUA provisions, including implementing strict inventory control and record keeping, completing signed consent forms, and monitoring of adverse events.
- CDHS will coordinate development of educational materials and distance learning scripts for just-in-time training and refresher courses on vaccine delivery protocols and vaccine administration techniques for persons who do not normally administer vaccines.
- To decrease morbidity and mortality associated with pandemic influenza, CDHS will continue to work with LHDs to encourage pneumococcal vaccination of persons aged 65 years and older and other persons recommended by the Advisory Committee on Immunization Practices (ACIP).

- In collaboration with federal authorities, CDHS will coordinate vaccine distribution plans with tribal entities and bordering jurisdictions including other states and Mexico.
- CDHS will coordinate vaccine distribution plans with other state agencies (e.g., the California Departments of Corrections and Rehabilitation, Mental Health, and Developmental Services).
- CDHS will communicate, and when appropriate, coordinate vaccine activities with Baja California.

6.4.3 WHO Phase 5 - Substantial Pandemic Risk: Larger clusters but still limited human-to-human transmission; sustained community transmission is possible

Vaccine may still not be available or may be in limited supply. Preparations should be made to begin vaccinating target populations according to the pre-designated priority groups (see Attachment 6A).

- CDHS will communicate with other appropriate stakeholders (e.g., large health plans such as Health Net and Kaiser Permanente, the California Pharmacists Association, the California Hospital Association, the California Medical Association, the Emergency Medical Services Hospital Association, and LHDs) and the public to provide updates on the status of vaccine production, priority group designations, and guidelines for whom to vaccinate (see Appendix 9).
- CDHS will review and refine plans prepared in phases 3 and 4 for delivery and storage of vaccine as it becomes available to CDHS, including:
 - evaluating additional mechanisms of vaccine delivery (e.g., SNS, vendors via centralized CDC distribution system, or direct from manufacturers), receipt and transport of vaccine, and whether vaccine distribution is limited to the public health sector (likely in the initial phase), the private sector, or a combination of the two;
 - establishing other vaccine storage depots as available/needed, in addition to storage site(s) described in phases 3 and 4;
 - regularly evaluating allocation of vaccine to LHDs depending on population and priority group strategies;
 - continuing coordination with EPO for secure delivery of vaccine from CDHS storage facilities to LHDs, which are responsible for vaccine distribution within their jurisdictions;
 - providing updated protocols to LHDs for receiving, storing, and administering vaccine, including encouraging identification of additional mass vaccination clinic sites as needed, formation of MOUs with those sites, and ensuring adequate security of clinic sites and storage facilities;
 - working with LHDs to assess the local availability of vaccine administration supplies as described in phase 3 and 4; and

- encouraging LHDs to continue coordinating with their OES Operational Area MHOACs, RDMHC/S, and CDHS JEOC to assess available local surge capacity to administer vaccination and to staff vaccination clinics.
- If vaccine is administered under IND protocol, CDHS will ensure strict inventory control and record keeping, completion of signed consent forms, and monitoring of adverse events via a paper or electronic system. The IZB will be the primary coordinating body for any vaccine administered under IND protocol.
- CDHS will ensure adequate staffing and communications for VAERS for monitoring vaccine safety, including:
 - designating a CDHS VAERS coordinator;
 - establishing a team to review and monitor for adverse events once vaccination begins;
 - if needed, implementing and refining a database system for monitoring adverse events and reporting/interfaces with VAERS;
 - alerting LHDs on the need to report adverse events to VAERS; and
 - establishing a support hotline to assist new VAERS users and users encountering problems.
- CDHS will review current guidelines for determining vaccination priority groups. Based on available supply, surveillance data, and epidemiologic information, CDHS will review and reprioritize as appropriate in consultation with CDC guidelines, the DCDC PIWG, and the CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization Strategies (see Attachment 6A), including:
 - updating the estimate of high-risk and priority individuals needing vaccination; and
 - coordinating with recommendations for vaccination priority groups, updating estimates by jurisdiction, and distributing to LHDs.
- CDHS will coordinate the development and distribution of educational and mass media materials and distance learning scripts for just-in-time training and refresher courses to broadcast to LHDs (see Appendix 9).
- CDHS will use epidemiologic studies of vaccine effectiveness to determine whether changes are needed in recommendations on vaccine formulation, dose, or schedule. CDC will coordinate these studies nationally and CDHS will collaborate with CDC on these studies when feasible.
- CDHS will communicate, and when appropriate, coordinate vaccine activities with Baja California.

6.4.4 WHO Phase 6 - Pandemic Period: Increased and sustained transmission in the general population

Vaccine may become more widely available during this phase. CDHS will begin facilitating procurement, coordination, and distribution of any available vaccine.

- CDHS will continue to work with LHDs, the OES Operational Area MHOACs, RDMHC/S, and CDHS JEOC to assess available local surge capacity and communication needs to administer vaccination and staff mass vaccination clinics.
- Based on available supply, surveillance data, and epidemiologic information, CDHS will continue to review and reprioritize target groups to receive vaccine as appropriate in consultation with CDC guidelines, the CDC PIWG, and the CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization Strategies (see Attachment 6A), including:
 - updating the estimate of high-risk and priority individuals needing vaccination; and
 - coordinating with recommendations for vaccination priority groups, updating estimates by jurisdiction, and distributing to LHDs.
- CDHS will review surveillance data for changes in risk factors that could require modification of recommendations for priority groups receiving vaccine.
- CDHS will monitor VAERS data for evidence of adverse reactions to the influenza vaccine and report findings routinely to CDC.
- CDC may revise or develop an updated VIS detailing the risks and benefits of the vaccine.
- CDHS will continue distributing available vaccine to LHDs that will be responsible for distributing, allocating, and vaccinating priority groups within their jurisdictions (including allocation to local hospitals as needed). Close collaboration between public and private healthcare providers will be essential.
- CDHS will assist LHDs in modifying existing standing orders for vaccine administration. These standing orders must include: dosage, site of administration, contraindications to vaccination, precautions to vaccination, and response to anaphylaxis and must be signed by the local health officer or agency director.
- CDHS will communicate, and when appropriate, coordinate vaccine activities with Baja California.
- CDHS, working through the JEOC PIO and the Office of Public Affairs (OPA), will provide frequent updates on vaccine availability and the determination of priority groups for conveyance to other stakeholders, partners, and the public (see Appendix 9).

6.4.5 WHO Postpandemic Period

- CDHS will provide a detailed retrospective characterization of the pandemic, and evaluate the efficacy of containment measures and emergency management strategies.
- In anticipation of a possible second pandemic wave, CDHS will continue statewide surveillance and mass vaccination programs as vaccine becomes more readily available, with the goal of vaccinating all California residents.
- CDHS will participate in the evaluation of all aspects of the targeted and mass vaccination programs, including vaccination coverage for first and second doses, priority groups and difficult to reach populations, monitoring of adverse events, and results of special studies to evaluate vaccine efficacy.

Attachment 6A - Pandemic Influenza Vaccine Prioritization Plan

6A.1 Background

Pandemic influenza threatens to cause mass illness and death in California as well as significant economic and social disruption. Vaccination is a key prevention strategy for controlling influenza and represents a critical control measure for decreasing the health consequences of a pandemic; however, supply will be limited early in the pandemic. The California Department of Health Services (CDHS) developed a pandemic influenza prioritization process plan to determine which target populations in California will be designated for initial vaccination.³

A comprehensive vaccine priority plan is critical for the State because:

- California will likely face a pandemic influenza outbreak sometime in the future; and
- a vaccination strategy will help limit the number of persons who may become ill and die, and will also limit the degree of social and economic disruption within the State.

The CDHS Immunization Branch (IZB) formed the CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization⁴ comprising public health and medical care professionals, emergency planners, hospital administrators, physicians, academics, infectious disease experts, a bioethicist, and the University of California, Berkeley Center for Infectious Disease Preparedness (CIDP). This group developed a process to advise CDHS on vaccine and antiviral related issues during a pandemic. CDHS contracted with the University of California, Berkeley Center for Infectious Disease Preparedness (CIDP) to help develop a prioritization plan.

6A.1.1 No Comprehensive Prioritization Process Currently Exists

In November 2005, the U.S. Department of Health and Human Services (HHS) released national vaccination priority recommendations. These recommendations are broad-based and HHS advised state and local health departments to create highly specific prioritization plans that specifically define priority groups, identify occupational categories and sub-categories within each broad priority designation, and select implementation strategies to deliver vaccine to priority groups. Several international organizations, foreign countries, and states have prepared pandemic influenza vaccination prioritization plans, but these plans fail to use a multidimensional approach.⁵

A review of currently published state and federal prioritization plans revealed that they are limited in two key areas: 1) defining and incorporating the appropriate inputs into the prioritization process; and 2) articulating a well-developed methodology. These two limitations are discussed below.

³ See the CIDP [Pandemic Influenza Vaccine Prioritization Plan](http://www.idready.org/pandemic_influenza/index.html) webpage for complete project overview and all supplemental documents (Weblink: www.idready.org/pandemic_influenza/index.html).

⁴ A subgroup of the CDHS Joint Advisory Committee on Public Health Preparedness.

⁵ A review of international, national, and state vaccination plans yielded seven documents from the following sources: the World Health Organization (WHO), the United States, Canada, Germany, Minnesota, Utah, and Wisconsin.

6A.1.1.1 Lack of Consideration for Prioritization Inputs

Existing state and federal plans do not clearly and consistently identify intervention goals, determine vaccination criteria, and define target populations to be prioritized. Systematically considering these three components is critical to the prioritization process. Existing state and federal plans demonstrate the following limitations regarding prioritization inputs.

- **Lack of consensus on intervention goals:** There is no consensus on the main goals of an influenza mass vaccination intervention. The specified goals within existing plans include minimizing health consequences (e.g., reducing mortality and morbidity, slowing disease transmission, maintaining healthcare systems, protecting those at highest risk); minimizing social disruption (e.g., ensuring integrity of social infrastructure, maintaining vital community services, maintaining essential services); and minimizing economic loss. While most plans include these goals, they are not consistently defined and are prioritized differently between plans. Furthermore, no plan clearly states the rationale for choosing these three intervention goals, or their relative importance.
- **Inconsistent vaccination criteria:** A lack of consensus on intervention goals has led to ambiguity about the criteria for determining who qualifies for vaccination. Approximately half of the state and federal plans reviewed do not document any criteria used in the prioritization process. The plans that document criteria offer no rationale for the criteria chosen and no plan evaluates any given criteria to identify which was most important to the prioritization process.
- **Ambiguous target group definitions:** Though current state and federal plans recommend similar groups and individuals for prioritization, the plans define their target groups differently and many plans do not clearly link these population groups to the criteria that qualify these groups to receive vaccine.

6A.1.1.2 Incomplete Documentation of Prioritization Methodology

Existing state and federal plans demonstrate the following limitations regarding documentation:

- **Lack of a systematic analytical process:** No state or federal plan presents a systematic and transparent decision-making process with evidence-based justifications. All plans document the target groups recommended for prioritization along with a list of rationales that supports the inclusion of that group.
- **Lack of ranking schemes:** The HHS recommendations and three state vaccination plans develop rank-ordered lists, but none of these plans describe the process used to assign specific rankings nor do they describe an implementation strategy for allocating vaccine within and between the target groups.

6A.1.2 Principles of the Prioritization Planning Process

Given the lack of a detailed federal plan or an analytically rigorous prioritization process for the State to leverage, CDHS developed its own rigorous approach toward prioritization planning with five key principles.

- The plan will be systematic and based on a logical methodology to identify alternatives

and project outcomes.

- The plan will be justifiable and based on epidemiologic, social science and ethics literature and supported by best practices research.
- The plan will be flexible and can be adjusted based on the changing epidemiologic characteristics of a pandemic.
- The plan will be adaptable and can be applied to different populations in different settings.
- The plan will be transparent and clearly defined with expert opinion and feedback.

6A.1.3 Choosing an Analytical Method

CDHS developed the Decision Analysis Scoring Tool (DAST). The DAST is a multi-dimensional decision-making tool that simultaneously analyzes multiple goals, criteria, and alternatives to develop an optimal prioritization scheme. This tool will assist CDHS in making decisions regarding who should receive vaccine during the different stages of an influenza pandemic.

The DAST, based on an Analytic Hierarchy Process (AHP), is a “choice-based” modeling technique that helps decision-makers allocate resources across competing alternatives.⁶ The DAST uses the AHP process to evaluate target groups within competing vaccination criteria and assigns a numerical score to each population group based on how well it matches the criteria. The DAST will produce a rank-ordered list of target groups prioritized for influenza vaccination to be implemented within the state.

6A.2 Assumptions

CDHS used the following assumptions to develop a comprehensive prioritization plan for California.

- Demand for influenza vaccine will far outstrip supply during the early stages of a pandemic. The demand for vaccine will equal the entire California population (about 37 million) multiplied by the number of recommended vaccine doses. The supply will equal approximately 480,000 doses per week.⁷ Therefore, approximately one percent of the California population will be able to receive a dose of vaccine per week after distribution begins.
- Shortages of antiviral medications will dictate their use for treatment rather than prophylaxis. Therefore, the distribution and use of antivirals will likely not affect demand for vaccine.
- CDHS will be responsible for distributing vaccine to the local health departments (LHDs) during the early stages of an influenza pandemic. The federal government will control

⁶ “Choice-based” modeling is a technique that forces decision makers to choose an option from a list of alternatives based on their opinions or preferences.

⁷ The Centers for Disease Control and Prevention (CDC) estimates that once the pandemic influenza virus strain is identified it will take about four to six months to produce the vaccine. At this time, 3-5 million doses will be supplied for the U.S. population and distributed to the states. CDC will distribute this vaccine supply based on total state population as well as statewide target group population estimates.

and allocate vaccine and the healthcare sector will not be able to directly purchase vaccine.

6A.3 Decision Analysis Scoring Tool (DAST) Methodology

The DAST process is conducted in four stages.

6A.3.1 Stage 1. Identify and Define DAST Inputs

The key inputs into the prioritization process (intervention goals, vaccination criteria, direct determinants, and target groups) were identified and defined. These inputs are incorporated into the DAST survey and will be used to generate a rank-ordered prioritization list. Figure 1 presents a schematic of the process for defining DAST inputs.

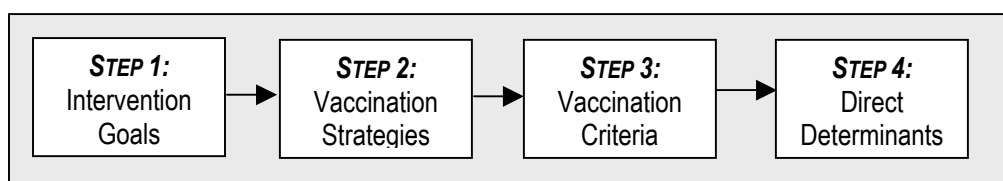


FIGURE 1: Defining DAST Inputs

6A.3.1.1 Identify Intervention Goals

- **Selecting intervention goals**

Selection of intervention goals that the State seeks to optimize is a critical step in the prioritization process. These goals inform both the selection of vaccination strategies and the development of vaccination criteria. The three primary goals for vaccine intervention are:

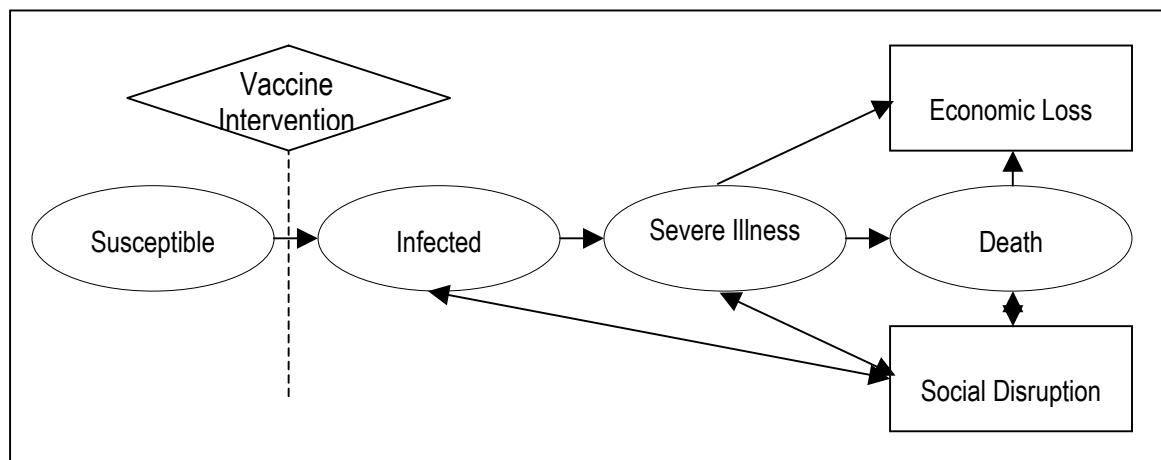
- minimizing health consequences: the ability of the intervention to reduce the number of severe illnesses and deaths caused by complications of pandemic influenza;
- minimizing social disruption: the ability of the intervention to reduce disruption in essential community services and to minimize social chaos and distress caused by pandemic influenza; and
- minimizing economic loss: the ability of the intervention to reduce the extent of economic losses caused by reductions in production and consumption of goods and services due to a pandemic.

- **Rationale for primary focus on minimizing health consequences**

The primary goal of the CDHS Pandemic Influenza Vaccination Plan is to minimize health consequences by slowing transmission and preventing influenza infection and severe illness. Vaccines provided to populations before they become infected increase the likelihood of avoiding disease leading to direct consequences (e.g., severe illness and death). Focusing intervention efforts on reducing the direct health consequences reduces indirect consequences (e.g., economic loss and social disruption).

CDHS used an epidemiologic model based on pandemic influenza was used (Figure 2). This model details the transmission dynamics of pandemic influenza, as well as the interactions between health consequences, social disruption, and economic consequences. This model serves as the methodologic framework for the development of the CDHS prioritization process.

FIGURE 2: Pandemic Influenza Transmission Model



6A.3.1.2 Select Vaccination Strategies⁸

All possible approaches toward allocating limited medical resources are identified and translated into relevant vaccine rationing strategies, then evaluated to determine their appropriateness for use during a pandemic.

- **Identifying rationing approaches and converting them into strategies**

There are two main theoretical approaches to rationing limited medical resources – utilitarianism and egalitarianism. Utilitarian approaches aim to create the greatest good for the greatest number of people. These principles aim to raise the general welfare of society rather than allocate resources to those in greatest need. Within this context, egalitarian approaches focus on maintaining or restoring equality for the persons in need of medical care. CDHS identified five utilitarian and five egalitarian principles to develop into relevant vaccination strategies. Both the theoretical approaches and relevant vaccination strategies are described below.

⁸ Refer to Supplemental Document: “An Analysis of Theoretical Approaches to Rationing” available at www.idready.org/pandemic_influenza/SUPPLEMENTAL_DOC_A.pdf for a complete discussion and evaluation of rationing strategies.

Theoretical Utilitarian Approach	Relevant Vaccination Strategy	Description
Principle of medical success	Ration by probability of successful immunization	This strategy would favor those for whom vaccination has the highest probability of preventing severe influenza illness and/or death.
Principle of immediate usefulness	Ration to those who perform essential emergency response roles	This strategy favors groups of individuals who are involved in the emergency response. Based on professional role.
Principle of conservation	Not applicable	Rationing to “conserve resources” does not apply to the vaccine situation because everyone will receive the same number of doses. Since there is no differentiation in amount of resources required by each person, this strategy can be eliminated from further analysis.
Parental role principle	Ration to those who perform a caretaker role	This strategy favors individuals who provide primary home care for children, elderly, and the unwell.
Principle of general social value	Ration to those who perform an essential community role	This strategy favors groups of individuals who are essential to maintaining social and economic continuity. Based on professional role.
Theoretical Egalitarian Approach	Relevant Vaccination Strategy	Description
Principle of saving no one	Do not ration vaccine	This strategy means that no vaccine would be distributed.
Principle of medically neediest	Ration by medical and prevention needs	This strategy favors those groups who are most likely to transmit influenza virus to susceptible populations as well as those groups at high risk of developing severe illness and/or death.
Principle of general neediness	Ration to those with minimal access to medical care	This strategy favors those who have poor access to medical care services based on their income, wealth, employment levels, and residency status.
Principle of queuing	Ration via queuing	This strategy gives priority to those who are first in line for the vaccine.
Principle of random selection	Ration via lottery	This strategy would give everyone within California an equal chance of being selected for vaccination.

- **Evaluation of Strategies**

Selection of relevant vaccination strategies to achieve all three intervention goals is essential. In addition, the strategies must meet appropriate ethical, legal, political feasibility, and implementation standards. Therefore, five tests were developed to determine which rationing strategies were used as DAST inputs. The five tests are described below:

1. **Does the strategy meet the intervention goals?**

Each strategy must reduce the number of illnesses and deaths in order to be included for further analysis. As described previously, focusing on reducing health consequences will also minimize social and economic consequences.

2. **Is the strategy fair and just?**

Assessments of “justice” were based on bioethicist Gerald Winslow’s assessment of the ten theoretical principles toward allocating scarce medical resources detailed in his book *Triage and Justice*.⁹

3. **Is the strategy legal?**

Strategies that are legitimate exercises of public health authority defined in the California Health and Safety Code were considered “legal.”

4. **Is the strategy politically feasible or appropriate given the circumstance?**

Political feasibility was determined by whether the strategy would be accepted by the majority of the population, including both constituents and political representatives.

5. **Can the strategy be practically implemented given the emergency circumstances?**

Ease of implementation was judged based on whether the target groups designated for vaccination under the appropriate strategy could be easily identified.

All tests were evaluated on a points-based rating scale (Reference Document 6A.7.1 *Summary of Rationing Strategy Tests* describes the rating methodology and presents the results from this analysis). To be included in the DAST model, each strategy must pass all five tests. Four of the nine strategies passed and were deemed appropriate.¹⁰ They are listed below:

- rationing to those who perform an essential emergency response role;
- rationing by medical and prevention needs;
- rationing by probability of successful immunization; and
- rationing to those who perform an essential community role.

⁹ Winslow, Gerald. *Triage and Justice*. Berkeley: University of California Press, 1982.

¹⁰ This analysis was reviewed by a bioethicist to validate the second test “justice” and by CDHS IZB to validate the third and fourth tests, “political feasibility” and “implementation.”

6A.3.1.3 Develop Vaccination Criteria

To understand who will qualify for prioritization under the vaccination strategies listed above, vaccination criteria for each of the four vaccination strategies were developed. Emphasis was given to criteria that focused on minimizing health consequences. Members of the CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization approved the definitions and provided feedback. The criteria identified for each of the strategies is listed below:

Relevant Strategy	Criteria
Medical and prevention needs	<ul style="list-style-type: none"> ▪ Risk of transmission ▪ Risk of infection ▪ Risk of complication
Probability of successful immunization	<ul style="list-style-type: none"> ▪ Vaccine effectiveness
Performs essential emergency response role	<ul style="list-style-type: none"> ▪ Provides DIRECT service essential to carrying out an effective emergency response ▪ Provides SUPPORT service that is necessary for carrying out an emergency response
Performs essential community role	<ul style="list-style-type: none"> ▪ Provides DIRECT service essential to maintaining social and economic continuity

6A.3.1.4 Identify Direct Determinants of Each Criterion

Each criterion is further broken down into direct determinants that detail the characteristics that target groups must demonstrate to qualify for vaccination under that criterion. (6A.7.2 Criteria Definitions presents the definitions and direct determinants for all seven criteria.)

6A.3.1.5 Identify Target Population Groups¹¹

CDHS identified populations meeting one or more of the DAST criteria that will be considered for prioritization during the different stages of an influenza pandemic. The target population groups were selected based on health-related characteristics and professional roles.

Role-based target groups perform roles that are essential to the emergency response and/or to maintain critical infrastructure. These groups are classified by the industry in which they work, the occupational setting where they work, and in some cases, the occupation or job title they hold. Health-characteristic related target groups include persons with certain health-related characteristics that place them at high risk of developing influenza complications and/or persons who can transmit influenza to high risk persons. These target groups are classified by their health status or health characteristic and in some cases by their age.

¹¹ Refer to Supplemental Document B “Target Population Group Profiles” available at www.idready.org/pandemic_influenza/SUPPLEMENTAL_DOC_B.pdf for detailed descriptions and population estimates of each of the target groups.

The target population groups fall into five main categories:

Population Category	Target Population Description
I. Health-related characteristics	Includes persons with a variety of health characteristics that may place them at higher risk of developing influenza complications or at higher risk of transmitting the virus to persons unable to receive the vaccine.
II. Professional roles within HEALTH industries	Includes members of the healthy adult population participating in the labor force within health service and public health professions.
III. Professional roles within PUBLIC ADMINISTRATION, JUSTICE, and SAFETY INDUSTRIES	Includes members of the healthy adult population participating in the labor force within public administration, justice, and safety professions.
IV. Professional roles within NON-HEALTH COMMERCIAL industries	Includes members of the healthy adult population participating in the labor force within non-health and commercial industries.
V. Other healthy populations	Includes persons with NO underlying health characteristics that put them at high risk of influenza complications and those who are NOT EMPLOYED in the professional occupations and industries identified above.

(6A.7.3 List of Target Groups presents the list of target population groups.)

6A.3.2 Stage 2. Develop and Administer DAST Survey

6A.3.2.1 Develop DAST Survey

A cross-sectional survey was developed to test the model with the CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization.¹² The survey process is based on the principles of the Delphi method.¹³ The three main objectives of the survey are to:

- determine the relative importance of the identified criteria in achieving the intervention goals;
- determine how well each target group meets the relevant vaccination criteria; and

¹² Refer to Supplemental Document C “DAST Survey Questionnaire” (Phase I) available at www.idready.org/pandemic_influenza/SUPPLEMENTAL_DOC_C.pdf for the complete survey questionnaire.

¹³ The Delphi technique is a multistage process that seeks input from a panel of experts through multiple rounds in order to reach consensus on complex decisions. Once completed, the survey responses are analyzed and presented to the decision makers to provide information and elicit feedback. This iterative process facilitates consensus by allowing all panel members to participate and creating an environment where respondents can provide confidential feedback via a survey questionnaire [13, 13].

- assess the strength and usability of the survey to prioritize populations for influenza vaccine.

6A.3.2.2 Establish Prioritization Score Calculation Method¹⁴

To generate a prioritization list from the data collected in the DAST survey, the analytical method to calculate the rankings is performed in two steps: (1) calculate criterion scores; and (2) calculate prioritization scores.

1. Calculate criterion scores

The target group's criterion scores include two key inputs, the criterion weight and the strength of match between target group and criterion. The criterion weight serves as the numerical point value for the criterion. The criterion weight is determined from information collected in the DAST survey. Criteria with higher weights are considered more important and have the greatest affect on determining a target group's criterion scores.

The strength of match between the target group and a specific criterion depends on how many direct determinants the target population fulfills. The more direct determinants the group fulfills, based on data from the DAST survey, the greater the strength of the match. Fulfilling a critical determinant will have a greater impact on the strength of the match than fulfilling a non-critical determinant. To calculate a target group's criterion score, the criterion weight is multiplied by the strength of the match, and this process of calculating criterion scores is repeated for each criterion.

Figure 3 below shows a simple example of how points are allocated to "Public Safety and Justice – Police Protection/Law Enforcement" target group on the "Provides Direct Emergency Response Service" criterion.

FIGURE 3: Point Allocation Example

"Provides Direct Emergency Service" Criterion Weight (8.18)	*	Strength of Match (53%)	=	Total Points (4.67)
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2. Calculate final prioritization scores

Each target group's criterion scores are summed across all seven criteria to determine a group's "final prioritization score." This calculation process was repeated for all target groups.

¹⁴ Refer to Supplemental Document D "Prioritization Score Calculation Method" available at www.idready.org/pandemic_influenza/SUPPLEMENTAL_DOC_D.pdf for a detailed explanation of how prioritization scores are calculated.

6A.3.2.3 ADMINISTER SURVEY

A self-administered pilot survey was distributed via email to the CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization.

6A.3.3 Stage 3. Analyze DAST Results and Develop Priority List

The results from the pilot DAST survey were analyzed and prioritization scores were determined. A sensitivity analysis was performed to determine the robustness of the survey results. Finally, the list was re-organized into a rank-ordered prioritization list based on the target groups' final prioritization scores. CDHS made no prioritization decisions on the basis of this pilot survey. The process requires that large numbers of persons representing many different occupational, health, and public group complete the survey. The survey process will be completed by August 2006.

6A.3.3.1 Analyze DAST Survey Results¹⁵

- **Derive criteria weights**

The pilot survey data was analyzed to determine the average weight for each criterion. The survey instrument asked respondents to rate the importance of the criteria on an eleven point scale (0=least important and 10=most important). Most of the respondents felt that all the criteria were important but some criteria were deemed more important than others. 'Providing direct emergency response services' was considered the most important criterion with a value of 8.8 points. This was followed by 'risk of transmission' (7.9) and 'providing support emergency response services' (7.1). 'Risk of complication' and 'providing essential community services' were approximately of equal importance (6.6). 'Vaccine effectiveness' (6.3) and 'risk of infection' (5.9) were least important.

- **Calculate criterion scores**

The data from the survey was analyzed to determine the average number of points that each target group received for each criterion. As described above, the criterion scores are based on the weight of the criterion and the strength of the match.

- **Calculate prioritization score**

Each target group's criterion scores were summed across all seven criteria to determine a group's final prioritization score.

- **Evaluate survey instrument**

The final section of the survey asked respondents to evaluate the survey questionnaire and determine its usability. Overall respondents determined that the survey fulfilled its key objectives and provided sufficient information to adequately answer the questions. Eighty-two percent of respondents expressed confidence in using the DAST survey

¹⁵ Refer to Supplemental Document E "DAST Survey Analysis" available at www.idready.org/pandemic_influenza/SUPPLEMENTAL_DOC_E.pdf for the complete analysis of survey results and calculation of final prioritization scores.

results to produce a rank ordered prioritization list. This demonstrates that most of the respondents support the DAST methodology and are likely to accept the results.

6A.3.3.2 Rank-order the Target Population Groups

The prioritization scores from the pilot survey were rearranged into a rank-ordered list of priority groups. Those with the highest scores were ranked first and should be the first to receive the vaccine. Medical care and emergency response professionals dominate the top third of the priority list. These target groups received points on more vaccination criteria than the other groups and they received more points per criterion than the other groups. For example, the top twenty groups fulfilled six of the seven criteria and had an average “strength of match” rate of 70 percent on these criteria.

Medical care system support workers, select essential workers, and select individuals with medical and prevention needs comprise the middle third of the priority list. These groups met between four and six criteria and had an average “strength of match” rate of 55 percent on these criteria.

The remaining essential workers, remaining individuals with medical and prevention needs, and the remaining healthy adult population dominate the bottom third of the priority list. These groups met between two and six criteria and had an average “strength of match” rate of 47 percent.

6A.3.3.3 Perform Sensitivity Analysis¹⁶

A Monte Carlo sensitivity analysis was performed to estimate the affect of the criteria weights on the target group rankings. The objective of this analysis was to determine the range of prioritization scores each population group received when the criteria weights were simultaneously altered. We assumed the criteria weights followed a normal distribution, with the baseline value equaling the mean weight given by DAST respondents.

Each target population’s prioritization score is sensitive to uncertainty in all of the criteria under which they qualified for vaccination. This is largely due to the small sample size upon which the analysis was conducted. Generally, uncertainty in the weight of the ‘vaccine effectiveness’ criteria had the largest impact on the prioritization scores; however, there is little pattern in how the other criteria affected each of the 69 prioritization scores.

The Monte Carlo simulation revealed that simultaneously varying the criteria weights over a range of plausible values has little impact on the rankings. Sixteen target groups (23.2 percent of total) changed ranking. The majority of these (11 target groups) moved only one spot. Three groups moved two spots, one group moved three spots, and one group moved four spots. The remaining groups had minor differences in their final prioritization score, but maintained their original rank.

¹⁶ Refer to Supplemental Document F “DAST Sensitivity Analysis” available at www.idready.org/pandemic_influenza/SUPPLEMENTAL_DOC_F.pdf for the complete sensitivity analysis results and discussion.

6A.3.4 Stage 4. Recommend Implementation Strategy

The final stage of the DAST methodology is to select the best strategy to allocate the vaccine using the DAST prioritization list. An analysis was performed to select the 'optimal' vaccine implementation strategy for the State.¹⁷ The "optimal" strategy is one that takes into account multiple components and best meets the relevant implementation criteria.

6A.3.4.1 Identify Implementation Options

The CDHS vaccine implementation plan comprises six components. Each component consists of several implementation options. The analysis examined each component separately to select the option that fulfills the implementation criteria listed in the next section. A summary of the implementation components and options is presented below.

Component	Component Description	Component Option	Component Option Description
Organization of Priority List	"Organization of priority list" refers to whether the target groups will be categorized (by setting or health characteristic) or left as 69 distinct entities.	1. Distinct target groups	Target groups remain as 69 distinct entities (as defined on the DAST survey).
		2. Categorized target groups	Target groups will be grouped by work setting or health characteristic
Degree of Coverage	"Degree of coverage" refers to the portion of a target group that must be vaccinated before moving onto the next group.	1. Full coverage	Vaccinate 100% of a target group before moving onto vaccinating the next target group.
		2. Partial coverage	Vaccinate part of a target group (1-99%) before moving onto vaccinating the next target group.
Stratification of Priority List	"Stratification of priority list" refers to the order in which target groups will be prioritized for vaccine.	1. Strict rank order	Vaccinate target groups based on DAST rank order.
		2. Tiered grouping	Organize target groups into "tiers" based on DAST rank order. All target groups within a tier are equally prioritized.
Distribution Approach	"Distribution approach" refers to the method that will be used to allocate	1. Standard distribution	Allocate incoming shipments of vaccine supply equally across

¹⁷ Refer to Supplemental Document G "Implementation Strategy Analysis" (to be developed) available at (Weblink TBD) for complete analysis results and discussion.

Component	Component Description	Component Option	Component Option Description
	incoming shipments of vaccine to equally prioritized target groups.		target groups of equal priority.
		2. Proportionate distribution	Allocate incoming shipments of vaccine supply based on the number of people within a target group.
Dose Allotment	“Dose allotment” refers to the number of doses the target group will receive before moving onto the next group.	1. Full allotment	All target groups within a tier receive two doses (full allotment) prior to distributing first doses to the next tier.
		2. Partial allotment	All target groups on the priority list in all tiers receive one dose (partial allotment) prior to distributing a second dose to any target group.
		3. Full allotment for “critical” or “most needy” tiers	Target groups in the critical or most needy tiers will receive two doses (full allotment) first. Target groups within non-critical tiers will receive the vaccine after this occurs.
Distribution Mechanism	“Distribution mechanism” refers to the mechanism that will be used to administer the vaccine to individuals within a target group.	1. Queue (first-come, first-serve)	Establish a line and select individuals for vaccine who are first in line.
		2. Lottery	Establish a lottery to randomly select persons within target group.

6A.3.4.2 Identify Implementation Criteria

The implementation strategies were evaluated on six criteria. These criteria were broken down into a series of characteristics, which describe the elements that the implementation option **must demonstrate** in order to meet that criterion.

Not all characteristics are relevant to all options. The implementation options which best meets the *relevant* characteristics of each criterion will be recommended to the CDHS for use during a pandemic influenza emergency. A brief discussion of each implementation criterion is presented below.

- Meets intervention goals: Strategy minimizes health, economic and social consequences by promoting an effective pandemic emergency response and preserving critical infrastructure in the State. Specifically, optimal strategy favors the highest ranked target groups, promotes workers interdependencies and promotes an effective emergency response.
- Just/Fair: Optimal strategy balances promoting equal access to the vaccine with efficiently allocating the limited amount of vaccine.
- Legitimate: Optimal strategy is a legitimate use of public health power.
- Politically Acceptable: Optimal strategy is rational, simple, places no undue burden on the public, and has been approved for use by other jurisdictions.
- Feasible to implement: Optimal strategy requires a limited amount of additional analysis, incurs reasonable costs, and can be efficiently administered by responsible agencies.

6A.3.4.3 Recommend Optimal Implementation Strategy

CDHS is currently evaluating the implementation options against the relevant criteria. CIDP has developed a draft implementation strategy for the DAST priority list. These draft recommendations must be evaluated and approved by the CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization and CDHS before being included in the prioritization annex.

Component	Recommended Option
Component 1 Organization of Priority List	<i>To be determined</i>
Component 2 Degree of Coverage	<i>To be determined</i>
Component 3 Stratification of Priority List	<i>To be determined</i>
Component 4 Distribution Approach	<i>To be determined</i>
Component 5 Dose Allotment	<i>To be determined</i>
Component 6 Distribution Mechanism	<i>To be determined</i>

6A.4 DAST Limitations¹⁸

The limitations of the DAST methodology are presented below along with a series of recommendations on ways to minimize them in a subsequent administration of this tool.

¹⁸ Refer to Supplemental Document H “Discussion of DAST Limitations” available at www.idready.org/pandemic_influenza/SUPPLEMENTAL_DOC_H.pdf for a complete discussion of the limitations of the DAST methodology and recommendations regarding how to minimize these limitations.

	Limitation	Description	Methods to Minimize Limitation
Stage 1. Identify and define DAST inputs	Potential for missing inputs	Soliciting feedback from a homogenous group of stakeholders may have resulted in the development of an incomplete list of goals, criteria, or target groups.	Administer DAST survey to a larger and heterogeneous sample of respondents and incorporate feedback into the DAST.
	Potential for overly complex input definitions	While effort was made to define inputs in layperson terms, it is possible that the definitions and descriptions of the inputs (goals, criteria, target groups) are too technical for respondents lacking medical knowledge.	Respondents' comments asking for clarification on key inputs will be incorporated into the DAST.
	Inconsistent target group categorization	Because some groups are defined as an entire industry (food manufacturing) whereas medical care and public health groups are defined within a specific setting or occupation (medical care practitioners in hospital settings), it is difficult for survey respondents to evaluate target groups on the same criteria	Separate priority group list into a "between group" list (that defines groups exclusively at the industry level) and a series of "within group" lists (that define target groups at the occupational level within an industry or setting.)
Stage 2. Develop and administer DAST survey	Small and homogenous survey sample	The DAST prioritization list incorporated the judgments of only 11 experts. This sample size is too small to accurately measure the relative importance of criteria weights and to calculate the target groups' final prioritization scores.	Administer survey to a larger a more representative sample of emergency preparedness experts in the State.
	Survey instrument may not accurately reflect range of individual opinions	The survey instrument provided a limited range of answer categories and this forced respondents to make an absolute assessment of whether target groups matched or did not match a direct determinant	Survey instrument could provide a greater range of answer categories to incorporate strong and weak opinions.

	Limitation	Description	Methods to Minimize Limitation
Stage 3. Analyze DAST results and develop priority list	Difficult for some respondents to assess relative importance of criteria	Because the rating scale exercise asked respondents to assign points to criteria on an eleven point ordinal scale, it was difficult for respondents to determine the criteria's relative importance to one another.	Follow-up with respondents who evaluated the rating exercise unfavorably and incorporate their feedback into the DAST survey instrument.
	High level of uncertainty in determining whether target groups meet certain criteria	Respondents may have felt that the information needed to evaluate target groups on certain criteria was not known and could not be reasonably estimated and therefore they did not answer the questions.	Obtain feedback on how respondents used detailed information provided with the questionnaire to evaluate target groups. Organize group discussions with influenza preparedness experts to determine which professional groups play a role in the State's pandemic response effort.
	Inability to estimate epidemiologic impact of an influenza pandemic	Epidemiologists cannot predict the epidemiologic impact of the next pandemic with any great certainty. Therefore, the current DAST results may not reflect the epidemiologic impact of a pandemic.	Incorporate pandemic epidemiologic data into the DAST when it becomes available.
	Inability of DAST to evaluate individuals who fall into multiple target groups	<i>DAST divides target populations into mutually exclusive groups.</i> In reality, individuals can belong to multiple target groups. This simplification in the model would lead to some individuals receiving a lower DAST prioritization score than their status merits.	Individuals that are in multiple groups will be categorized with the group that receives the highest prioritization score and is ranked the highest.

	Limitation	Description	Methods to Minimize Limitation
	Use of survey questionnaire does not allow for consensus decision making	Use of a confidential self administered survey questionnaire does not allow group members to share knowledge on the roles and risks of target groups nor does it allow members to express strong opinions or influence others decisions in order to gain a consensus.	Create a structured group level discussion that allows members to share knowledge on the roles and risks of target groups as well as allow members to influence others decisions to gain a consensus.
Stage 4. Recommend Implementation on Strategy	Lack of well-documented implementation strategies in other jurisdictions	No existing vaccination plan includes recommendations on how the jurisdiction will implement their prioritization list to allocate vaccine. In particular, the plans did not detail the degree of coverage each target groups should receive, the distribution approach, dose allotment, or distribution mechanism.	Interview key decision makers within the CDC and HHS to determine if implementation recommendations will be included in the upcoming federal pandemic influenza preparedness plan. Lead a focus group or survey local emergency responders to determine whether these recommendations will be politically acceptable and can be implemented during a pandemic

Limitation	Description	Methods to Minimize Limitation
Certain criteria are more important determinants of an optimal implementation strategy than others	The implementation analysis did not determine the relative importance of the five implementation criteria to one another. For this reason, the numerical scores for the options within each component are conservative estimates that mask the importance of select criteria.	Survey CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization members by developing a question which asks respondents to rate the importance of the criteria and use the average point values to derive the criterion weights and calculate the scores for each option. Engage in a structured group discussion with the CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization and CDHS IZB to determine whether some criterion should be deemed more important or “dominant” than others within each component’s analysis.
Certain characteristics are more important determinants of implementation criterion than others	Each of the six implementation criteria was broken down into a series of characteristics. For this reason, the numerical scores for the options within each component are conservative estimates that mask the importance of select characteristics.	Engage in a structured group discussion with the CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization and high level staff within CDHS IZB to determine whether some criterion should be deemed more important or “dominant” than others within each component’s analysis.

Limitation	Description	Methods to Minimize Limitation
Inability to estimate and quantify the effectiveness of implementation options	The implementation analysis did not use economic and/or epidemiologic models to predict the effectiveness of implementation options. As a result, the current implementation recommendations can be questioned on their ability to meet the intervention goals and their feasibility.	Develop an economic and epidemiologic simulation model to determine the cost effectiveness/ cost benefit of vaccinating the target groups on the DAST list under each implementation option.

6A.5 References

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6A.6 Vaccination Plan Supplemental Documents

A. An Analysis of Theoretical Approaches to Rationing

This document presents a complete discussion of the theoretical approaches to rationing limited medical resources, a detailed description of how they were converted into relevant vaccine allocation strategies, and a full evaluation of the rationing strategies.

(Weblink: www.idready.org/pandemic_influenza/SUPPLEMENTAL_DOC_A.pdf)

B. Target Population Group Profiles

This document contains detailed profiles of the 69 target population groups that likely meet one or more of the vaccination criteria. These target groups appear on the DAST survey.

(Weblink: www.idready.org/pandemic_influenza/SUPPLEMENTAL_DOC_B.pdf)

C. DAST Survey Questionnaire (Phase I)

This document is the complete paper version of the DAST survey that was administered to the CDHS Joint Advisory Committee on Pandemic Influenza Vaccine and Antiviral Prioritization on June 21, 2005.

(Weblink: www.idready.org/pandemic_influenza/SUPPLEMENTAL_DOC_C.pdf)

D. Prioritization Score Calculation Method

This document reviews how the results of the DAST survey will be used to derive vaccine prioritization scores for target groups.

(Weblink: www.idready.org/pandemic_influenza/SUPPLEMENTAL_DOC_D.pdf)

E. DAST Survey Analysis

This document reviews the results from the DAST survey in greater depth.

(Weblink: www.idready.org/pandemic_influenza/SUPPLEMENTAL_DOC_E.pdf)

F. Sensitivity Analysis

This document reviews in detail how population group prioritization scores vary when the criteria weights are simultaneously altered.

(Weblink: www.idready.org/pandemic_influenza/SUPPLEMENTAL_DOC_F.pdf)

G. Implementation Strategy Analysis (to be completed)

This document evaluates implementation options on relevant criteria in order to select an “optimal” implementation strategy for the State. (Weblink: TBD)

H. Discussion of DAST Limitations

This document describes the limitations of the DAST methodology and presents recommendations on improvements that can be made to minimize these limitations.

(Weblink at: www.idready.org/pandemic_influenza/SUPPLEMENTAL_DOC_H.pdf)

6A.7 Reference Documents

6A.7.1 Summary of Rationing Strategy Tests

Each strategy was allocated between zero and two points, with zero points indicating that the strategy does not pass the test and two points indicating that the strategy is completely acceptable based on the given criteria. Receiving one point indicates that either there are some reservations about the strategy or that the acceptability of the strategy is uncertain.

TABLE 1: FILTERING THROUGH STRATEGIES TO RATIONING LIMITED MEDICAL RESOURCES

Strategy	Test 1: Minimizes illness/death	Test2: Fair/just strategy	Test 3: Legal	Test 4: Politically feasible/ appropriateness	Test 5: Feasible to implement	Final Score	Pass or Fail
Utilitarian Strategies							
Ration by probability of successful immunization	2	2	2	2	1	9	Pass
Ration to those who perform essential emergency response role	2	2	2	2	2	10	Pass
Ration to those in a caretaker role	1	0	2	0	0	3	Fail
Ration to those who perform essential community role	1	1	2	1	2	7	Pass
Egalitarian Strategies							
Do not ration vaccine	0	--	--	--	--	0	Fail
Ration by medical and prevention needs	2	2	2	2	2	10	Pass
Ration to those with limited access to medical care	1	2	2	0	0	5	Fail
Ration via queuing	1	1	2	0	2	6	Fail
Ration via lottery	1	2	2	0	2	7	Fail

6A.7.2 Criteria Definitions

Below are more detailed descriptions of each of the criteria. These descriptions include the criteria definition, the direct determinant, and the scaling questions, which were used to identify the target population groups who will be prioritized for vaccination under that criterion.

Category	Category Definition	Criteria	Criteria Definition	Direct Determinant
1. Medical and prevention needs	This category favors those groups who are most likely to transmit influenza virus to susceptible populations and/or those groups at high risk of developing severe illness and/or death.	Risk of complication	Once infected, the probability of developing severe illness and/or dying as a result of the disease. ¹⁹	<ul style="list-style-type: none"> Age Co-morbidity (other conditions affecting immune response)
		Risk of transmission	Once infected, the probability of transmitting the virus to a susceptible contact at high risk of influenza complications. ²⁰	<ul style="list-style-type: none"> Duration of infectiousness Frequency, closeness, and duration of contact with susceptible populations
		Risk of infection	The probability of becoming infected through close and/or prolonged contact with potentially infectious cases. ^{21,22}	<ul style="list-style-type: none"> Frequency, closeness, and duration of contact with potentially infectious cases
2. Probability of successful immunization	This category favors those for whom vaccination has the highest probability of medical success, e.g., preventing severe influenza illness and/or death.	Vaccine effectiveness	Ability of vaccine to prevent illness and death from pandemic influenza by promoting an effective immune response. ²³	<ul style="list-style-type: none"> Co-morbidity (other conditions affecting immune response) Age

¹⁹ Risk of complication will be based on epidemiologic evidence collected during interpandemic years. Risk of complication may change depending on the epidemiology of the influenza pandemic.

²⁰ Risk of transmission (Basic Reproductive number) is a function of number of susceptible contacts per unit time*transmission probability per contact*duration of infectiousness (Formula: $R_0 = cpd$). Therefore it cannot be determined whether the contact rate or the duration of infectiousness is the dominating factor.

²¹ Probability of influenza Infection cannot be determined. Therefore, onset of disease e.g. symptoms can be used to determine probability of infection.

²² For group comparison purposes, assume that there is complete disease susceptibility across all populations. Therefore, anyone who becomes infected with the influenza virus also develops disease

²³ Vaccine effectiveness depends on degree of similarity between inactivated virus and actual virus circulating in population. Estimates are based on vaccine efficacy during interpandemic years.

Category	Category Definition	Criteria	Criteria Definition	Direct Determinant
3. Performs essential emergency response role	This category favors those groups who provide essential services in launching a pandemic emergency response.	Provides DIRECT emergency response service	Provides DIRECT service essential to carrying out an emergency response.	Includes groups who perform the following activities: <ul style="list-style-type: none"> ▪ Directly provide services necessary to ensure vaccine is produced, distributed, disseminated, and administered among population ▪ Provide direct patient care and essential medical services ▪ Directly provides public health and/or front line emergency response services ▪ Role requires at least two years of advanced training and role cannot be easily or quickly replaced
		Provides SUPPORT emergency response service	Provides SUPPORT service that is essential to carrying out an emergency response.	Includes groups who perform the following activities: <ul style="list-style-type: none"> ▪ Directly SUPPORT those who provide services necessary to ensure vaccine is produced, distributed, disseminated, and administered among population ▪ Directly SUPPORT those providing patient care services by maintaining an operational medical care delivery system ▪ Directly support those providing public health and front line emergency response services by maintaining an operational emergency response system ▪ Role requires at least two years of advanced training and role cannot be easily or quickly replaced
4. Performs essential community role	This category favors those groups who directly provide a service that is essential to maintaining social continuity and reducing the threat of social chaos.	Provides essential community service	Directly contributes to social and economic continuity.	Includes groups that <ul style="list-style-type: none"> ▪ Perform life saving or live preserving roles outside of the pandemic emergency response ▪ Provide services in order to meet basic needs (food, water, energy, healthcare, shelter) of California residents and to ensure that the state functions ▪ Provide services in order to meet the basic financial needs of California residents and to ensure that the state functions ▪ Role requires at least two years of advanced training and role cannot be easily or quickly replaced

6A.7.3 List of Target Groups

Division I: Health-related characteristics²⁴

This group includes persons with a variety of health characteristics that may place them at higher risk of developing influenza complications as well as those who can transmit influenza to high risk persons. Specific groups within this division are the following:

A. People with underlying chronic medical conditions

1. Persons ages 2-17 years
2. Persons ages 18 -64 years
3. Persons ages 65+ years

B. Pregnant Women (all ages)

C. Infants and Toddlers

D. Primary household contact of children <6 months

1. PHHC ages 2-17 years
2. PHHC ages 18 - 64 years
3. PHHC ages 65+ years

E. Primary household contact of severely immunocompromised persons

1. PHHC ages 2-17 years
2. PHHC ages 18 - 64 years
3. PHHC ages 65+ years

Division II: Professional roles within HEALTH industries²⁵

Includes members of the healthy adult population (18+) participating in the labor force within medical care, public health, and commercial health professions. Specific groups within this division are the following:

A. Medical care service industry: This industry includes professionals working in the following medical care settings: general medical and surgical hospitals, psychiatric and substance abuse hospitals ambulatory care facilities, and nursing and residential care facilities.

1. Medical Care Practitioners
2. Medical Technicians and Aides
3. Medical Scientists and Laboratory Technicians
4. Mental Health and Social Service Providers
5. Healthcare System Support and General Support

²⁴ Health-characteristics are based on CDC descriptions of populations at high risk of influenza complications during interpandemic years.

²⁵ Industry, setting and occupation descriptions are based on the North American Industry Classification System (NAICS) definitions for 2002. See United States Census Bureau for complete list of industries and their definitions. <http://www.census.gov/epcd/naics02/naicod02.htm#N22>

B. Public Health Departments: Includes professionals working in a public health department setting. Includes public health workers employed in federal, state, and local health jurisdictions that have a role within the incident command structure (ICS) for infectious disease emergencies.

1. Pre-event Public Health Emergency Responders
2. Event oriented Public Health Emergency Responders
3. Non-emergency Public Health Professionals

C. Commercial Health Industries: Includes professionals working in the following commercial health settings:

1. Medical and diagnostic laboratories
2. Manufacturing - Medical and pharmaceutical manufacturing
3. Retail Trade - Pharmacies
4. Retail Trade - Other health and personal care stores
5. Death Care Services

Division III: Professional roles within Public Administration, Safety, and Justice

Includes members of the healthy adult population (18+) participating in the labor force within public administration, justice and safety professions. Specific groups within this division are the following:

A. Public Administration: Includes professionals working in the following government settings:

1. Executive Offices
2. Legislative Bodies and Offices
3. Tribal Governments
4. Public Finance Services

B. Public Safety and Justice: Includes professionals working in the following industries:

1. Judicial and Legal Services
2. Police Protection
3. Fire Protection/EMT
4. Corrections
5. Emergency and Disaster Management Services

Division IV: Professional roles within NON-HEALTH commercial industries

Includes members of the healthy adult population (18+) participating in the labor force within non-health and commercial industries. Specific groups within this division are the following:

A. Agriculture Industry

B. Information Industry

C. Educational Services

D. Financial and Insurance Services**E. Community Care Services**

1. Religious Organizations
2. Emergency Relief Services
3. Non-emergency Social Assistance Services

F. Transportation and Warehousing Services

1. Postal Services
2. Air, Rail, Water, and Truck Transportation & Support Activities
3. Transit and Ground Passenger Transport
4. Couriers and Messengers
5. Warehousing and Storage

G. Manufacturing Industries - Food Manufacturing only**H. Retail Trade - Food, Beverage, and Grocery Stores only****I. Utility Industries****J. Waste Management and Remediation Services****Division V: Other healthy populations**

Includes persons with NO underlying health characteristics that put them at high risk of influenza complications and those 18+ who are NOT EMPLOYED in the professional occupations and industries identified above. Specific groups within this division are the following:

A. Healthy Children, Ages 2 - 5**B. Health Children, Ages 6 – 17****C. Healthy Adults, Ages 18 – 64****D. Healthy Adults, Ages 65+**

Appendix 7 – Pandemic Influenza Antiviral Drug Program

7.1 Introduction

As of fall 2005, antiviral drugs for influenza consist of two classes: adamantanes or M2 ion-channel inhibitors (amantadine and rimantadine), and neuraminidase inhibitors (zanamivir and oseltamivir). Adamantanes are active against influenza A and neuraminidase inhibitors are active against influenza A and B. Appropriate use of antiviral drugs during an influenza pandemic may reduce morbidity and mortality and also may be useful in limited attempts to contain or slow the spread of small outbreak clusters of novel influenza virus. Because a large or uncoordinated demand early in a pandemic or interpandemic phase could rapidly deplete commercial and other existing supplies of antiviral drugs useful for pandemic influenza virus strains, advance planning for coordinated dissemination of antiviral drugs is critical.

Both amantadine and rimantadine are available in proprietary and generic formulations, both as capsules/tablets and syrup. Amantadine also is used to treat symptoms of Parkinson's disease. Amantadine is inexpensive and produced in the United States and internationally by multiple generic pharmaceutical manufacturers. Several manufacturers also produce rimantadine.

By contrast, oseltamivir and zanamivir are each only licensed for production by a single manufacturer, and as of fall 2005, are not available as generic formulations in the United States. Zanamivir is indicated for treatment of uncomplicated influenza A and B viral illnesses in adults and pediatric patients aged seven and older, but is not advised for treating influenza in patients with underlying airway diseases. Oseltamivir is indicated for treating influenza in patients one year of age and older, and also for prophylaxis against influenza.

Current federal recommendations for treating a suspected case of avian influenza A (H5N1) or another novel strain of influenza recommend using oseltamivir or zanamivir administered as early as possible and ideally within 48 hours of onset of symptoms. Neuraminidase inhibitors are preferred for treatment over amantadine and rimantadine because the majority of avian influenza A (H5N1) viruses currently affecting humans are resistant to these antiviral drugs, or rapidly develop resistance to them compared with resistance to neuraminidase inhibitors.

7.1.1 Use of Antiviral Drugs in Treatment of Influenza

Both adamantanes and neuraminidase inhibitors are approved for treatment of influenza in persons over one year of age. The usual recommended duration of treatment is five days. Controlled studies have found that when administered for treatment within 48 hours of illness onset, both drugs are effective in decreasing viral shedding and reducing the duration of illness of influenza A by approximately one day compared with placebo. No prospective trials have documented reductions in influenza complications such as pneumonia or the need for hospitalization.

However, recent pooled analysis of ten randomized placebo-controlled studies have suggested the efficacy of neuraminidase inhibitors in reducing complications of influenza, including lower respiratory tract complications, and influenza-associated hospitalizations, in healthy persons aged 13 to 65 years and persons at increased risk for influenza complications.¹ While these

¹ Kaiser, L et al., Impact of oseltamivir treatment on influenza-related lower respiratory tract complications and hospitalizations. Arch Intern Med. 2003 Jul 28;163(14):1667-72.

studies were unable to directly assess the impact on mortality, given their impact on pneumonia and hospitalizations, such an effect is likely.

Several cautions should be emphasized in generalizing from these pooled data. The large majority of persons studied were not at high risk of influenza complications and those at increased risk were not severely immunocompromised. Also, as therapy generally was started early (at about 24 hours after symptom onset), the impact would likely be less for persons who start therapy later. Finally, most study participants were treated as outpatients and the impacts of therapy could be different for persons who are more severely ill at the time treatment was begun (see Attachment 7A).

7.1.2 Use of Antiviral Drugs in Prophylaxis of Influenza

Prophylaxis with both classes of antiviral drugs has been shown to be as effective as vaccine (70-90 percent) in preventing infection with non-pandemic strains of influenza virus when administered in the following situations: 1) during the period when influenza is present in a community, 2) for a shorter period following exposure in a household or institutional setting versus no antiviral drug treatment, or 3) following vaccination until the development of protective immunity. Some studies, including those conducted during influenza pandemics, have shown lower prophylactic efficacy. Although this difference may be due to a delay in starting prophylaxis, it may also be attributed to the immune status of a patient with no prior illness or vaccination with that influenza subtype. Currently adamantane drugs are approved for use as prophylaxis in persons over one year of age; neuraminidase inhibitors for persons aged 13 or older (see Attachment 7A).

7.1.3 Adverse events

Adverse events are more common with adamantanes than with neuraminidase inhibitors. Adamantanes have been associated with central nervous system toxicity such as lightheadedness, difficulty concentrating, nervousness, insomnia, and seizures in patients with pre-existing seizure disorders. Toxicity is more likely among persons with renal insufficiency, older persons, and those with seizure disorders or psychiatric illness. Rimantadine use has been associated with substantially fewer CNS side effects than amantadine.

Oseltamivir appears to be well tolerated, associated primarily with nausea and vomiting. Oseltamivir required dose modification in patients with impaired renal function (creatinine clearance < 30) and is not indicated in children less than one year of age because of evidence of adverse effects in animal studies.

7.1.4 Resistance

The therapeutic use of amantadine and rimantadine has been associated with the rapid development of resistant viruses, resulting from point mutations that correspond with a single amino acid change in the target protein. Resistant variants may replace susceptible strains after two to four days of treatment. In some settings, resistance has been found in more than 30 percent of those treated. Drug-resistant and drug-susceptible strains spread equally well. Resistance renders both treatment and prophylaxis ineffective.

Treatment with neuraminidase inhibitors has been associated with a low incidence of emergence of resistance detected late during therapy and not associated with clinical deterioration. Because these drugs have been available only for a few years and their use has

not been widespread, there has been limited selective pressure for resistance. In vitro studies have found that cross-resistance occurs between the neuraminidase inhibitors, but does not affect susceptibility to adamantanes.

7.2 Objectives

The objectives of the California Department of Health Services (CDHS) pandemic influenza program for antiviral drugs are to:

- establish a flexible strategy for the judicious and appropriate use of antiviral drugs in the event of a pandemic, with the goal of decreasing morbidity and mortality and maintaining essential services;
- procure, allocate, distribute, and administer antiviral medication as rapidly, efficiently, and equitably as possible to priority groups and populations during a pandemic; and
- establish methods for monitoring safety and investigating adverse events of antiviral drugs.

7.3 Assumptions and Planning Principles

- Given the expected demand during a pandemic, or if the public perception of risk from a pandemic is high, supply shortages for antiviral drugs likely would occur.
- Antiviral drug use is not a strategy for altering the overall course of a pandemic. Modeling studies suggest that the amount of drug needed for this effect would be far greater than the supply.
- In the setting of confirmed human-to-human transmission, once detection of the first case of novel virus infection in the United States occurs, CDHS will review federal guidelines on the appropriate use of antiviral drugs and revise guidance accordingly.
- In the Baja California border region there are more than 200 million border crossings a year. In the event of a pandemic influenza, great numbers of people will likely cross the border to receive health care or purchase medications, including antivirals.
- CDHS will communicate activities pertaining to antiviral drug prioritization, administration, monitoring, evaluation, and public education to Baja California health officials as appropriate.

7.3.1 Antiviral Drug Delivery and Administration

- If requested and approved, the Centers for Disease Control and Prevention (CDC) will deploy the Strategic National Stockpile (SNS) to the designated Receiving, Storage, and Staging (RSS) warehouse as determined by CDHS. The Emergency Pharmaceutical Services Unit (EPSU) will receive antiviral drugs from CDC and oversee storing and distribution of SNS material.
- CDHS, with guidance from the Division of Communicable Disease Control (DCDC) Pandemic Influenza Work Group (PIWG), the CDHS Joint Advisory Committee on

Pandemic Influenza Vaccine and Antiviral Prioritization Strategies², and CDC, will allocate any federally delivered or purchased, and/or State-controlled stockpiles of antiviral drugs to pre-specified priority groups for treatment and/or prophylaxis.

- The Emergency Preparedness Office (EPO) is responsible for site security and securing necessary escorts for SNS material transported on California roads and highways.
- EPSU will provide, according to the CDHS SNS Plan, antiviral drugs and other SNS materials to local health departments (LHDs), which have pre-identified potential distribution and dispensing sites/treatment centers and will allocate supplies to target priority groups within their jurisdictions. Because of the need to implement therapy early in the course of illness, strategies that make drugs available at the point of care are most likely to be successful. For example, antiviral drugs could be distributed to hospitals in quantities that reflect number of acute care beds and emergency department visits. Close collaboration between public and private healthcare providers will be essential.
- LHDs will track and account for all antiviral drugs distributed to them. LHDs will also ensure the proper storage, handling, and administration of antiviral drugs.
- CDC will develop a standard statement detailing the risks and benefits of antiviral use to decrease the impact of novel virus infection.
- In some situations, antiviral drugs may be administered and distributed under Investigational New Drug (IND) protocols, requiring informed consent before administration and monitoring for possible adverse events after administration. For example, IND protocols may be used if it is deemed that the benefits of administering the drug to infants less than one year of age, because of a high risk of fatal outcome with novel virus infection, outweigh the risk of possible adverse events from the drug. Alternatively, antiviral drugs may be administered under the U.S. Food and Drug Administration's (FDA) Emergency Use Authorization (EUA), which will minimize the administrative burden to facilitate streamlined and efficient administration of these drugs. The FDA will determine which, if any, federally mandated protocols are required for dispensing of the antiviral drugs.

7.3.2 Monitoring and Evaluation of Antiviral Drug Coverage

- LHDs, with CDHS support, will have the primary responsibility for monitoring and evaluating activities within their jurisdictions.
- LHDs will document that recipients are in a priority group designated to receive the drug.
- LHDs will have the primary responsibility for data entry into databases that include summary information for antiviral drug use such as priority group designation and date/week of distribution.
- LHDs will report summary data to the CDHS Immunization Branch (IZB) regarding numbers of individuals in different priority groups who have received antiviral drugs. EPO will distribute and track antiviral drugs that are distributed from the SNS.

² A subcommittee of the CDHS Joint Advisory Committee on Public Health Preparedness (JAC).

7.3.3 Tracking for Adverse Reactions to Antiviral Drugs

Education efforts prior to and during a pandemic should include information about antiviral drugs, rationale for use and prioritization, contraindications, precautions, drug-drug interactions, and potential adverse events.

- FDA's MedWatch system (<http://www.fda.gov/medwatch>) will monitor adverse events following use of antiviral drugs in a pandemic. LHDs may submit reports to the FDA electronically, by fax, or by telephone.
- Antiviral drugs administered and distributed under IND or EUA protocols may require a separate monitoring system and database for more thorough tracking and follow up of possible adverse events.

7.3.4 Monitoring for Antiviral Drug Resistance

- As large numbers of patients use antiviral drugs, rates of resistance are likely to increase.
- The risk of resistance during a pandemic is likely to be high because antiviral drug use would be widespread in the United States and in the countries from which the pandemic strain spread, highlighting the importance of on-going resistance monitoring.
- Because antiviral drug resistance would reduce or eliminate the benefits of prophylaxis or therapy, ongoing monitoring by CDC and the Viral and Rickettsial Disease Laboratory (VRDL), if resources are available, for drug resistance among novel virus strains will be critical.

7.3.5 Prioritization Strategies for Limited Antiviral Drugs

CDHS will make specific recommendations regarding priority groups for receiving antiviral drugs for treatment and/or prophylaxis based on the following considerations discussed by the CDHS Joint Advisory Committee on Vaccine and Antiviral Prioritization Strategies and the DCCDC PIWG.

- If antiviral drug supply is limited, treatment will likely be a more efficient strategy than prophylaxis to reduce negative health impacts of a pandemic. This is because prophylaxis requires six to eight weeks or longer, depending on how long the novel virus is circulating in the community, and because large amounts of antiviral drug would be needed to provide prophylaxis to a group of people who, while at risk, may not become infected.
- Antiviral therapy is likely to have the greatest impact during a pandemic if it is targeted to those who, in the absence of treatment, would progress to hospitalization or death.
- Because the benefits of antiviral therapy are greater with a shorter interval between onset of symptoms and treatment, emphasis should be placed on early care and rapid diagnosis, particularly for those in designated priority groups.

- Based on existing data, therapy generally should be offered only to those who have been symptomatic for 48 hours or less. However, exceptions may include persons with illness requiring hospitalization or persons who are immunosuppressed and may have a prolonged period of active viral replication.
- Although young, healthy adults experienced high morbidity and mortality in the 1918 pandemic, very young persons, elderly persons, and persons with underlying disease are still also considered to be at high risk of death in a future pandemic.
- Based on data from annual influenza outbreaks, higher rates of lower respiratory tract complications, hospitalization, and death may occur among persons in defined risk groups, including young children.
- Antiviral usage strategies must be flexible and responsive to antiviral supply and the epidemiology of the pandemic. Epidemiologic investigations performed by CDC and others early during the pandemic will be important to help determine the groups who are at highest risk for adverse health outcomes and the age-specific case fatality rate.
- Depending on recommendations of the CDC, the CDC PIWG, and the CDHS Joint Advisory Committee on Vaccine and Antiviral Prioritization Strategies, CDHS will consider alternative strategies to screen essential personnel for symptoms. For example, daily screening of healthcare workers and other essential workers at risk of exposure to novel virus infection for fever and/or respiratory symptoms can be instituted, with antiviral therapy offered to those who have been symptomatic for 48 hours or less.
- Because limited data suggest that therapy with neuraminidase inhibitors reduce lower respiratory tract complications and hospitalizations, and because adamantanes are more likely to induce antiviral resistance when used for therapy, neuraminidase inhibitors may be the preferred choice for treatment (if the pandemic strain is susceptible³).
- In some situations, antiviral drug use as prophylaxis may be considered (e.g., if an isolated, localized outbreak is detected early on in the pandemic and there is the possibility of containment with the use of non-medical containment measures and antiviral drug prophylaxis of a specific exposed population, or more antiviral drug becomes available). Because of their greater availability and substantially lower cost, and because adamantanes often induce clinically significant resistance when used for therapy, adamantane use should be reserved for prophylaxis (if the pandemic strain is susceptible³).
- Initiation of pre- and postpandemic public education efforts by State and local public health partners will be required early on, regarding the rationale for established antiviral drug use priorities.
- CDHS and LHDs will need to work with private sector healthcare organizations and healthcare providers to educate providers and the public regarding target groups and

³ If a pandemic is caused by one of the strains of H5N1 avian influenza virus that is causing widespread avian and human outbreaks in Asia in 2004-2006, amantadines are not indicated for either prophylaxis or therapy, as those strains have been found to be resistant to the adamantines.

optimal antiviral drug use strategies. These efforts will increase the likelihood that private sector antiviral drug supply will be used to meet pandemic response goals.

7.4 CDHS Pandemic Response

7.4.1 WHO Phase 1 and Phase 2 - Interpandemic Period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals

No or limited vaccine is available. Antiviral drugs may be available in the private sector and in the public sector from the SNS, and possibly, a CDHS antiviral stockpile.

- CDHS will issue guidelines on the appropriate use and prescription of antiviral drugs during seasonal, non-pandemic influenza periods. These guidelines will also discourage against personal stockpiles of antiviral medications.
- CDHS EPSU, in collaboration with the Immunization Branch (IZB), will inventory pharmaceutical vendors and distributors to determine which companies distribute antiviral drugs and estimate quantities and time-line of supply.
- CDHS will investigate the feasibility of developing a State stockpile of antiviral drugs.
- CDHS will communicate activities pertaining to antiviral drug prioritization, administration, monitoring, evaluation, and public education to Baja California health officials, as appropriate.

7.4.2 WHO Phase 3 and Phase 4 - Pandemic Alert Period: Human infection with no or very limited human-to-human transmission

No or limited vaccine is available. Antiviral drugs may be available in the private sector and in the public sector from the SNS, and possibly a CDHS antiviral stockpile.

- CDHS EPSU will communicate regularly with CDC and antiviral drug manufacturers and distributors to obtain updates on plans for augmented antiviral drug stockpiles, production, and distribution.
- CDHS will convene regular meetings between the DCDC PIWG and the Joint Advisory Committee on Vaccine and Antiviral Prioritization Strategies to develop recommendations on the prioritization for distribution of antiviral drugs in a pandemic, and to provide guidance to LHDs for distribution and prioritization within their jurisdictions.
 - This group will meet bimonthly to review and update recommendations based on current antiviral drug supply and updated global surveillance and epidemiologic data on characteristics of the novel virus.
 - In conjunction with the panel and using CDC and California Department of Finance population data, CDHS will determine approximate size of the priority populations.

- CDHS will develop and maintain a database with estimated numbers by jurisdiction and update it as the census changes.
- CDHS will develop and distribute protocols for distributing antiviral drugs, including:
 - developing delivery, storage, and distribution plans with LHDs;
 - determining allocation of antiviral drugs to LHDs based on population and priority groups;
 - arranging secure delivery of antiviral drugs from CDHS storage facilities to LHDs;
 - providing LHDs with updated protocols for receiving, storing, and administering antiviral drugs, including encouraging identification of distribution sites such as clinics or hospitals, formation of agreements with those sites, and ensuring adequate security of clinic sites and storage facilities;
 - providing LHDs with updated guidelines for administering antiviral drugs, based on recommendations from CDC and the CDHS Joint Advisory Committee on Vaccine and Antiviral Prioritization Strategies (e.g., treatment of severely ill patients who are hospitalized or at risk of severe complications, treatment of healthcare workers or other essential workers who develop symptoms detected by daily monitoring, or prophylaxis of specific exposed target populations or groups in an early, localized confirmed outbreak); and
 - using risk communication strategies to identify and explain justification for priority groups (see Appendix 9).
- CDHS will test database systems for monitoring antiviral supply, distribution, and administration, and resolving problems.
- CDHS will establish memorandums of understanding (MOUs) with pharmaceutical distributors to redistribute any stores of antivirals to sites as determined by CDHS or the RSSS warehouse in the event of an SNS deployment.
- CDHS will develop contingency plans for emergency distribution of unlicensed antiviral drugs using IND/EUA provisions, including strict inventory control and record keeping, completion of signed consent forms and monitoring of adverse events as required by the FDA.
- CDHS will develop pre-prepared messages targeting healthcare providers and the public regarding antiviral usage, including indications, dosages, best practices, adverse events, and rationale for use.
- CDHS will communicate appropriate antiviral use guidelines and distribution plans with Baja California, including any public communication activities.

7.4.3 WHO Phase 5 - Substantial Pandemic Risk: Larger clusters but still limited human-to-human transmission; sustained community transmission is possible

Vaccine may still not be available or exist in limited supplies and CDHS will begin facilitating procurement, coordination, and distribution of any available vaccine. Local and regional supplies of antiviral drugs will likely begin to be depleted.

- CDHS will communicate regularly with CDC, antiviral manufacturers, and distributors to obtain updates on plans for additional antiviral drug stockpiling, production and distribution.
- CDHS will communicate regularly with LHDs to review and revise antiviral administration and delivery plans, and provide updates on the status of antiviral supplies, production, priority group designations and guidelines for who will receive antiviral drugs.
- CDHS will communicate with other appropriate partners (e.g., large health plans such as Health Net and Kaiser Permanente, the California Pharmacists Association, the California Hospital Association, the California Medical Association, and the Emergency Medical Services Authority), stakeholders, and the public to provide updates on the status of antiviral supplies, production, and priority group designations and guidelines for who receives antiviral drugs (see Appendix 9).
- CDHS will review, refine, and implement plans for delivery, storage, and distribution of antiviral drugs as they become available to CDHS, including:
 - evaluating mechanisms of antiviral delivery, receipt and transport of vaccine;
 - regularly evaluating allocation of antiviral drugs to LHDs depending on population and priority group strategies;
 - continuing coordination with EPSU for secure delivery of antiviral drugs from CDHS storage facilities to LHDs, which are responsible for antiviral distribution within their jurisdictions;
 - providing LHDs with updated protocols for receiving, storing, and administering antiviral drugs, including encouraging identification of distribution sites such as clinics or hospitals, development of MOUs with those sites, and ensuring adequate security of clinic sites and storage facilities; and
 - providing LHDs with updated guidelines for administering antiviral drugs based on recommendations from the CDC, the DCDC PIWG, and the CDHS Joint Advisory Committee on Vaccine and Antiviral Prioritization Strategies (e.g., treatment of severely ill patients who are hospitalized or at risk of severe complications, treatment of healthcare workers or other essential workers who develop symptoms detected by daily monitoring, or prophylaxis of specific exposed target populations or groups in an early, localized confirmed outbreak).
- If antiviral drugs are administered under IND or EUA protocols, CDHS will ensure that strict inventory control and record keeping, completion of signed consent forms, and

monitoring of adverse events via a paper or electronic system is performed according to FDA requirements.

- CDHS EPO will implement any established MOUs with pharmaceutical distributors for redistribution of any existing stores of antiviral drugs to sites as determined by CDHS or the RSS warehouse in the event of an SNS deployment.
- CDHS will ensure adequate staffing and communications for FDA's MedWatch system. The Vaccine Adverse Effects Reporting System (VAERS) team will perform the following functions:
 - designating a CDHS MedWatch coordinator (can be the same as the VAERS coordinator);
 - establishing a team to review and monitor for adverse events, particularly for antiviral drugs given under IND protocol;
 - if needed, implementing and refining a database system for monitoring adverse events and reporting/interfaces with the MedWatch system;
 - alerting LHDs of the need to report adverse events to MedWatch system; and
 - coordinating with the Office of Public Affairs and EPO on a hotline to assist users unfamiliar with Medwatch and users encountering problems.
- CDHS will review guidelines for antiviral drug priority groups. Based on antiviral supply and surveillance and epidemiologic data, CDHS will reprioritize those who will receive antiviral drugs as appropriate in consultation with CDHS Joint Advisory Committee on Vaccine and Antiviral Prioritization Strategies. CDHS will update the estimates of high-risk and priority individuals by jurisdiction and distribute to LHDs.
- CDHS will distribute pre-prepared messages targeting healthcare providers and the public regarding antiviral usage indications, including information on dosages, best practices and adverse events, and to educate persons not in identified priority groups regarding the rationale for established priorities.
- CDHS and LHDs will continue working with private-sector healthcare organizations and providers to educate them regarding target groups and optimal antiviral drug use strategies.
- CDHS, in collaboration with CDC, will design and implement epidemiologic (e.g., case-control) studies to assess antiviral drug effectiveness and whether changes are needed in antiviral drug use strategies. CDHS will coordinate with antiviral drug resistance testing performed at VRDL and CDC.
- CDHS will communicate appropriate antiviral drug use guidelines and distribution plans with Baja California, including any public communication activities.

7.4.4 WHO Phase 6 - Pandemic Period: Increased and sustained transmission in the general population

Vaccine may become more widely available during this phase. CDHS will begin facilitating procurement, coordination, and distribution of any available vaccine. Local and regional supplies of antiviral drugs will likely begin to be depleted.

- CDHS will continue all pre-pandemic activities described above.
- Based on antiviral supply and surveillance and epidemiologic data, CDHS will continue to reprioritize antiviral drug use in consultation with the DCDC PIWG and the CDHS Joint Advisory Committee on Vaccine and Antiviral Prioritization Strategies. CDHS will continue to update estimates of high-risk and priority individuals by jurisdiction and distribute to LHDS.
- CDHS will review surveillance data for changes in risk factors that could require modifying recommendations for administering antiviral drugs to priority groups.
- CDHS will monitor MedWatch data for evidence of adverse reactions to antiviral drugs, particularly drugs given under IND protocol, and report findings to CDC.
- CDHS will continue to assess antiviral drug effectiveness to rapidly assess whether changes are needed in antiviral drug use strategies. CDHS will coordinate with antiviral resistance testing performed at VRDL and CDC.
- CDHS will continue efforts to educate the public, private sector healthcare organizations, and healthcare providers regarding target groups and optimal antiviral drug use strategies.
- CDHS will communicate activities pertaining to antiviral drug prioritization, administration, monitoring, evaluation, and public education to Baja California health officials, as appropriate.

7.4.6 WHO Postpandemic Period

- CDHS will attempt to provide a detailed retrospective characterization of the pandemic and to evaluate the efficacy of containment measures and emergency management strategies.
- Very few antiviral drugs will likely be available or used in this phase. In anticipation of a possible second pandemic wave, CDHS will continue statewide surveillance and mass vaccination programs as vaccine becomes more readily available, with the goal of vaccinating all California residents.
- CDHS will participate in the evaluation of all aspects of the antiviral drug distribution and allocation effort, including coverage of priority groups and difficult-to-reach populations, monitoring of adverse events, and results of special studies to evaluate antiviral efficacy and associated resistance.

Attachment 7A - Antiviral Drug Recommendations for Use

Antiviral Agent	Age Groups (years)				
	1-6	7-9	10-12	13-64	≥65
Amantadine^a (oral ¹)					
Treatment, Influenza A	5mg/kg body weight/day up to 150 mg in two divided doses ^b	5mg/kg body weight/day up to 150 mg in two divided doses ^b	100 mg twice daily ^c	100 mg twice daily ^c	≤100 mg/day
Prophylaxis, Influenza A	5mg/kg body weight/day up to 150 mg in two divided doses ^b	5mg/kg body weight/day up to 150 mg in two divided doses ^b	100 mg twice daily ^c	100 mg twice daily ^c	≤100 mg/day
Rimantadine^d (oral ¹)					
Treatment, ^e Influenza A	NA ^f	NA	NA	100 mg/day twice daily ^{c,g}	100 mg/day
Prophylaxis, Influenza A	5mg/kg body weight/day up to 150 mg in two divided doses ^b	5mg/kg body weight/day up to 150 mg in two divided doses ^b	100 mg twice daily ^c	100 mg twice daily ^c	100 mg/day ^h
Zanamivir^{i,j} (inhaler ¹)					
Treatment, Influenza A and B	NA	10mg twice daily	10 mg twice daily	10 mg twice daily	10 mg twice daily
Oseltamivir (oral ¹)					
Treatment, Influenza A and B	Dose varies by child's weight ^l	Dose varies by child's weight ^l	Dose varies by child's weight ^l	75 mg twice daily	75 mg twice daily
Prophylaxis, Influenza A and B	Dose varies by child's weight ^l	Dose varies by child's weight ^l	Dose varies by child's weight ^l	75 mg/day	75 mg/day

(From Prevention and Control of Influenza Recommendations of the Advisory Committee on Immunization Practices [ACIP], July 2005. Modified to reflect FDA approval of use of Oseltamivir for prophylaxis in children, December 2005.)

NOTE: Amantadine manufacturers include Endo Pharmaceuticals (Symmetrel (R)—tablet and syrup) and Geneva Pharms Tech (Amantadine HCL—capsule); USL Pharma (Amantadine HCL—capsule and tablet); and Alpharma, Carolina Medical, Copley Pharmaceutical, HiTech Pharma, Mikart, Morton Grove, and Pharmaceutical Associates (Amantadine HCL—syrup), and Sandoz. Rimantadine is manufactured by Forest Laboratories (Flumadine (R)—tablet and syrup); Corepharma, Impax Labs (Rimantadine HCL—tablet), and Amide Pharmaceuticals (Rimantadine HCL—tablet). Zanamivir is manufactured by GlaxoSmithKline (Relenza (R)—inhaled powder). Oseltamivir is manufactured by Roche Pharmaceuticals (Tamiflu (R)—tablet). Information based on data published by the U.S. Food and Drug Administration at www.fda.gov, accessed 3/30/2005.

¹ Common Side Effects:

Amantadine: CNS, GI. Rimantidine: CHS, GI (less often than amantadine). Oseltamivir: GI.
Zanamivir: Bronchospasm

^a The drug package insert should be consulted for dosage recommendations for administering amantadine to persons with creatinine clearance 50 ml/min/1.73m².

^b 5 mg/kg body weight of amantadine or rimantadine syrup = 1 tsp/2.2 lbs.

^c Children aged 10 years who weigh <40 kg should be administered amantadine or rimantadine at a dosage of 5 mg/kg body weight /day.

^d A reduction in dosage to 100 mg/day of rimantadine is recommended for persons who have severe hepatic dysfunction or those with creatinine clearance 10 mL/min. Other persons with less severe hepatic or renal dysfunction taking 100 mg/day of rimantadine should be observed closely, and the dosage should be reduced or the drug discontinued, if necessary.

^e Approved by FDA only for treatment among adults.

^f Not applicable.

^g Rimantadine is approved by FDA for treatment among adults. However, certain experts in the management of influenza consider it appropriate for treatment among children. (See American Academy of Pediatrics, 2003 Red Book.)

^h Older nursing-home residents should be administered only 100 mg/day of rimantadine. A reduction in dosage to 100 mg/day should be considered for all persons aged 65 years if they experience possible side effects when taking 200 mg/day.

ⁱ Zanamivir administered via inhalation using a plastic device included in the medication package. Patients will benefit from instruction and demonstration of the correct use of the device.

^j Zanamivir is not approved for prophylaxis.

^k A reduction in the dose of oseltamivir is recommended for persons with creatinine clearance <30 ml/min.

^l The dose recommendation for children who weigh 15 kg is 30 mg twice a day. For children who weigh >15 to 23 kg, the dose is 45 mg twice a day. For children who weigh >23 to 40 kg, the dose is 60 mg twice a day. And for children who weigh >40 kg, the dose is 75 mg twice a day.

Appendix 8 – Community Disease Control and Prevention

8.1 Introduction

This appendix addresses the containment of pandemic influenza in the community setting using non-medical strategies such as isolation, quarantine, and social distancing. Hospital-based infection control is covered in Appendix 4. Appendices 6 and 7, respectively, address vaccination and antiviral medications.

Non-medical containment measures will be critical in the early phases of a pandemic and will continue to be the principal prevention tools for mitigating the consequences of an influenza pandemic if vaccine and/or antiviral drugs are inadequate, due either to supply or efficacy shortcomings. These containment measures aim to reduce the risk of transmission by decreasing the probability of contact between infected and uninfected persons and decreasing the probability that contact will result in infection. Measures can be applied at the individual or community level and can be directed towards persons who are ill and persons who are well. Individual measures include isolation of ill patients (those with symptoms), quarantine and symptom monitoring of well persons who have had contact with ill persons, hand and respiratory hygiene, and use of personal protective equipment such as masks and gloves. Community measures include social distancing (such as restricting mass gatherings and closing schools), and limiting domestic and international travel. Attachment 8A and Tables 8A.1-8A.3 describe possible non-medical containment measures in more detail.

The applicability of specific non-medical containment measures will vary depending on the characteristics of the novel influenza virus, the assessment of risk, available resources, and the level of acceptance by the public. Guided by surveillance, laboratory, epidemiologic, and clinical data that are continuously reevaluated, the California Department of Health Services (CDHS) and local health departments (LHDs) will identify and implement the most appropriate measures at each phase of the pandemic to maximize impact on disease transmission and minimize impact on individual freedom of movement.

8.2 Objectives

The objectives of the CDHS pandemic influenza non-medical containment measures program are to:

- prevent human cases caused by a novel virus that has not yet established efficient human-to-human transmission;
- slow pandemic spread and gain time for strengthening preparedness measures, including augmenting vaccine and antiviral medication supplies; and
- reduce the morbidity, mortality, and economic and social disruption associated with the pandemic.

8.3 Assumptions and Planning Principles

- In the absence of adequate supplies of effective antivirals and effective vaccine, non-medical strategies are the primary means of mitigating the progression and impact of the pandemic.

- The effectiveness of most non-medical containment strategies depends on characteristics of the evolving virus including its pathogenicity (including infectious dose), principal mode of transmission (droplet or aerosol), onset and duration of viral shedding, attack rate (or infectivity) in different risk groups (especially by age), proportion of asymptomatic infections, and clinical presentation. Because human influenza has a short incubation period, a short generation time (average time between infection of the case and infection of the contacts), a high proportion of asymptomatic infections, and a non-specific clinical presentation, the utility of classic containment measures may be limited.
- In addition to effectiveness, the selection of non-medical containment strategies will depend upon feasibility (e.g., cost and availability of resources and supplies), ease of implementation within existing infrastructures, impact, and acceptance by the public. For example, quarantine requires specific accommodations, support, and resources to ensure the well being of all persons in quarantine.
- Most non-medical containment measures will have their greatest impact in the early pandemic phases, while some may have a role after the pandemic has begun. Opportunities for averting a pandemic or appreciably slowing its spread will likely end once efficient and sustained human-to-human transmission is established.
- Decisions about non-medical containment measures must be made in an atmosphere of considerable scientific uncertainty.
- Containment measures must be adapted to the epidemiologic context of each pandemic phase and recommendations regarding specific measures will change over the course of the pandemic. Once sustained human-to-human transmission is established, retiring those containment measures with decreased effectiveness is ethically justified to conserve resources for addressing the main public health objective of reducing the number of cases and deaths.
- If the emergence of the pandemic does not follow the exact phases listed in this document, the applicability of activities from prior phases will be assessed and implemented if supported by existing information. All applicable activities from previous phases will be continued, as appropriate. Alternatively, measures that were appropriate in the early phases may be discontinued later in the pandemic.
- Measures with limited effectiveness that the public chooses to adopt may be acceptable as long as they do not divert resources and supplies, are not discriminatory, and are clear and reasonable. For example, the benefit of wearing masks in community settings has not been established and may prove ineffective in limiting transmission. As long as this practice does not affect mask supplies needed for use in other settings, is not used in a discriminatory manner, and is not used as a substitute for other recommended measures, it will likely do no harm.
- Communication is a critical aspect of all emergency planning and response. Priority must be given to ensuring timeliness and accuracy of communication by all programs involved in planning for and responding to pandemic influenza and all other public health emergencies. Procedures and protocols for incorporating regular communication actions will be included into each phase of pandemic influenza planning and response to

facilitate sharing of information and messages within CDHS as well as with other response partners at the state and local level as well as with public messaging (see Appendix 9).

8.4 The decision-making process for recommendations about non-medical containment measures

The appropriateness of non-medical containment measures will vary depending on the assessment of risk, available resources, and level of public acceptance (Tables 8A.1, 8A.2). Decisions about the use and timing of non-medical containment measures should be supported by analysis of current clinical, laboratory, epidemiologic, and surveillance data from each phase of the pandemic. These data should include the number and characteristics of cases (especially the possible level of transmission in humans), available medical and public health resources, and the level of public acceptance (Table 8A.3).

In coordination with the Centers for Disease Control and Prevention (CDC), the Disaster Policy Council, and local health officers (LHOs), the Division of Communicable Disease Control (DCDC) Pandemic Influenza Work Group (PIWG) will meet regularly to review available data and develop (to the extent feasible) evidence-based criteria for making phase-specific recommendations. The PIWG will provide technical support and recommendations to the Director and CDHS executive staff on when isolation, quarantine, and social distancing measures are warranted.

If the Governor has not already proclaimed a state of emergency, CDHS will recommend this be done, when considering measures with widespread public health and societal impact. Even absent a Governor's proclamation of emergency, under California Health and Safety Code, CDHS has the legal authority to "require strict or modified isolation, or quarantine, for any case of contagious, infectious, or communicable disease, when this action is necessary for the protection of the public health..." or to "take measures as are necessary to ascertain the nature of the [contagious, infectious, or communicable disease] disease and prevent its spread." The Governor's Office of Emergency Services (OES) will coordinate implementation of activities and resources for measures that involve multiple agencies.

8.5 CDHS Pandemic Response Action Steps

8.5.1 WHO Phase 1 and Phase 2 - Interpandemic Period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals

- The PIWG will regularly assess available surveillance, laboratory, epidemiologic, and clinical data to describe the current influenza season.
- DCDC will update and distribute California-specific guidelines for control of interpandemic influenza in healthcare settings and in other congregate settings at the start of the respiratory season. Guidelines will include relevant excerpts from federal guidelines on vaccination, prophylaxis, and treatment recommendations. CDHS Licensing and Certification Division (L&C), the Department of Social Services (DSS), the Department of Mental Health (DMH), and LHDs will distribute the guidelines to healthcare facilities and individual providers.

- DCDC and the Office of Public Affairs (OPA) will promote respiratory hygiene and hand washing to the public.
- CDHS, the Office of Legal Services (OLS), and LHOs will develop and distribute model protocols and best practices for isolation and quarantine for both individual and community applications. Protocols should include voluntary agreements, model isolation and quarantine orders, criteria for voluntary versus mandatory compliance, procedures for medical evaluation, procedures for enforcing orders, and alternative arrangements for non compliant persons.
- CDHS, LHOs, and the Public Health Law Work Group will ensure all needed legal authorities exist and will ensure the ability to invoke local and state legal authority on isolation, quarantine, and social distancing strategies in a timely fashion.
- CDHS and LHDs will coordinate with partners and stakeholders who may be involved in enforcing mandatory isolation or quarantine orders in future pandemic phases.
- CDHS and LHDs will conduct drills and exercises on isolation and quarantine.
- CDHS Division of Environmental and Occupational Disease Control Occupational Health Branch (DEODC-OHB), together with the California Department of Food and Agriculture (CDFA), the California Department of Fish and Game (CDFG), and the California Occupational Safety and Health Administration (CAL/OSHA), will develop recommendations for control in animals and animal settings, including safety measures for persons who may have contact with potentially infected animals during culling and other at-risk activities.
- CDHS, working with LHDs, will identify facilities that may be used for isolation and quarantine of those persons who do not require hospitalization but whose residences do not accommodate isolation or quarantine.
- CDHS Emergency Preparedness Office (EPO), CDHS L&C Division, and OES, working with LHDs, will estimate current and surge supplies to support isolation, quarantine, and other containment measures (e.g., the number of isolation and quarantine facilities, support services to persons isolated/quarantined at home, availability of primary care givers, access to essential services, meal services, laundry services, masks, hygiene products, etc.).

8.5.2 WHO Phase 3 and Phase 4 - Pandemic Alert Period: Human infection with no or very limited human-to-human transmission

- The PIWG will review existing clinical, laboratory, surveillance, and epidemiologic data and in coordination with CDC and LHOs will make recommendations about non-medical containment strategies. The PIWG will provide technical support and make technical recommendations to the Director and CDHS executive staff on when isolation, quarantine, and social distancing measures are warranted. The recommendations will be distributed to LHDs as appropriate. Epidemiologic characteristics of the disease will determine the scope and duration of isolation and quarantine. Recommendations will address issues listed below.

- Patient isolation, including the applicability of strict or modified isolation of persons with suspected novel influenza virus and appropriate laboratory testing of specimens: Patients will likely be treated with a combination of standard, contact, droplet, and airborne precautions. While droplet precautions are generally recommended for interpandemic human influenza, airborne precautions may be considered for strains of novel influenza demonstrating increased transmissibility, during the initial stages of an outbreak of a novel strain of influenza, and as determined by other factors such as exposure during aerosol generating medical procedures.
- Managing close contacts: In certain situations, identifying and quarantining individuals or groups in contact with cases may be recommended. CDHS and LHDs will decide on and/or make recommendations about contact tracing and management on a case-by-case basis, in consultation with CDC. Decisions will be based on the likelihood that the suspected case is due to a novel influenza strain (based on exposure history or other risk markers), the likelihood that the virus is or may become transmitted from person to person with a moderate or high efficiency, and the feasibility of contact tracing given the likely short incubation period of the virus. If recommended, quarantine may be lifted as soon as the exposed contact has remained without symptoms for a complete incubation period (if known) or 10 days; other criteria may also be added (e.g., viral testing prior to release).
- Managing small clusters of human infection with novel influenza virus: Community-based measures that may be used to contain small clusters of infection with novel strains of influenza include targeted chemoprophylaxis and early detection of new cases. The PIWG, in coordination with LHOs, will make recommendations on a case-by-case basis; recommendations will depend in part on the potential to cover the entire affected area and the ability to rapidly administer antivirals. The use of antivirals is covered in Appendix 7.
- CDHS and LHDs will work with CDC quarantine stations and federal partners to evaluate and manage arriving ill travelers from affected regions who might be infected with a novel influenza virus and provide information to travelers arriving in the United States from affected regions about the symptoms and risk factors associated with the novel influenza virus, instructions for self-monitoring, instructions for isolation should symptoms develop, and mechanism for notifying public health officials in the event of illness.
- If animal sources are identified in California, CDHS DEODC-OHB, working with CDFA, CDFG, and CAL/OSHA, will implement animal control measures and animal-worker exposure control measures.
- CDHS (EPO, OLS, Disaster Policy Council) and LHDs will invoke local and state legal authority on isolation and quarantine, as needed, including those addressing the use of designated non-residential facilities to house cases and contacts that cannot or choose not to stay in their residences during isolation or quarantine.
- CDHS (DCDC and OPA) will continue to promote to the public respiratory hygiene and hand washing.

- CDHS EPO, working with LHDs, Operational Areas (OAs), Regional Emergency Operations Centers (REOCs), and OES, will monitor supplies to support isolation, quarantine, and other containment measures.
- If recommended by CDHS or CDC, all agencies and entities will continue other Phase 1-2 activities.

8.5.3 WHO Phase 5 - Substantial Pandemic Risk: Larger clusters but still limited human-to-human transmission; sustained community transmission is possible

- The PIWG will review existing clinical, laboratory, surveillance, and epidemiologic data. The PIWG, in coordination with CDC and LHOs, will revise recommendations about non-medical containment strategies. The PIWG will provide technical support and make updated technical recommendations to the Director and CDHS executive staff. The recommendations will be distributed to LHDs as appropriate. In addition to subject areas addressed in recommendations from Phase 3-4, Phase 5 recommendations may also address the issues listed below.
 - Focused measures to increase social distance (see Tables 8A.1 and 8A.2 below): CDHS and LHDs will make decisions and/or recommendations on the use of focused measures on a case-by-case basis, in consultation with CDC. Focused measures may be useful when there is limited transmission and most cases can be traced to a known transmission setting (a specific school or workplace).
 - Community-based measures (see Tables 8A.1 and 8A.2 below): CDHS and LHDs, in consultation with CDC, will make decisions and/or recommendations on community-based measures on a case-by-case basis. If some cases are children, CDHS and LHDs will consider broader school closures in the affected area.
- CDHS (EPO, OLS, Disaster Policy Council) and LHDs will invoke local and state statutes on isolation, quarantine, and social distancing, as needed.
- If recommended by CDHS or CDC, all agencies and entities will continue other Phase 3-4 activities.

8.5.4 WHO Phase 6 - Pandemic Period: Increased and sustained transmission in the general population

Once efficient and sustained human-to-human transmission occurs, non-medical containment strategies are unlikely to halt further spread, and priorities shift to reducing morbidity and mortality. CDHS will recommend containment measures in the context of available vaccine and antiviral medication, the level of public cooperation, resources available to implement and monitor compliance, and the severity of illness. CDHS will assess compliance with and the effectiveness of containment measures on an ongoing basis and make changes based on these factors and epidemiologic information.

- The PIWG will review existing clinical, laboratory, surveillance, and epidemiologic data. The PIWG, in coordination with CDC and LHOs, will revise recommendations about non-

medical containment strategies and identify measures that should be terminated. The PIWG will provide technical support and make updated technical recommendations to the Director and CDHS executive staff. The recommendations will be distributed to LHDs as appropriate. Recommendations may address the issue listed below.

- Patient isolation: Patients should continue to be separated from persons who are well to the extent feasible.
- Managing close contacts: Because their usefulness and feasibility will be limited, contact tracing and quarantine will likely not be used during this phase.
- Community-based containment measures: CDHS and LHDs will use community based containment measures on an as-needed basis, in consultation with CDC. Options include quarantine of groups of exposed persons or measures that effect parts of or the entire community.
- CDHS (EPO, OLS, Disaster Policy Council) and LHDs will invoke local and state legal authority on isolation, social distancing, and community-wide quarantine, as needed.
- If recommended by CDHS or CDC, all agencies and entities will continue other Phase 5 activities.

8.5.5 WHO Postpandemic Period

CHDS will:

- resume interpandemic measures after all waves of Phase 6 have ceased; and
- to the extent possible, evaluate the efficacy of non-medical containment measures during Phases 3-6.

Attachment 8A - Non-Medical Containment Measures: Definitions, Examples, and Considerations

The two most fundamental strategies for non-medical containment are isolation and quarantine (Table 8A.1). Isolation separates or restricts movement or activities of an ill person with contagious disease to prevent transmission to others. Quarantine restricts movement and activities or separates well persons believed to have been exposed to infection, to prevent transmission of diseases, should these persons develop disease. While isolation typically applies to an individual, quarantine can apply to an individual, a group such as those exposed at a specific place or gathering, or a wider population or geographic level.

Isolation and quarantine are optimally implemented voluntarily, following directions of healthcare providers and health officials. However, in California, both local and state health authorities have the authority to compel isolation and quarantine of individuals and communities when necessary to protect the public's health. These authorities are described in greater detail in the Core of this plan and in the Health Officer Practice Guide for Communicable Disease Control in California (Public Health Law Work Group) available at: <http://www.dhs.ca.gov/ps/dcdc/dcdcindex.htm>.

In addition to these two main strategies, other non-medical containment strategies include the use of physical barriers and hygiene measures to limit transmission (e.g., masks, gloves, respiratory hygiene, hand hygiene, other disinfection measures). These strategies are based on principles of infection control and are covered in greater depth in Appendix 4: Infection Control. To be most effective, containment measures should be implemented in "packages" that include a mix of strategies tailored to the epidemiologic context of the pandemic phase.

Table 8A.1: Non-medical containment measures: definitions, examples and considerations*

Measure	Definition	Examples and considerations
Individual-level containment measures	Measures applied on the individual (person) level as opposed to the group or community levels	Isolation of individual patients; quarantine of their close contacts
Isolation	The separation of infected persons from other persons for the period of communicability in such conditions as will prevent transmission of the agent. Strict isolation is confinement of the isolated individual to a room with a separate bed, with direct and room contact only with persons taking care of the individual. There must be appropriate disinfection and disposal of bodily excretions, secretion, garments, and objects in contact with the isolated individual. Persons caring for the isolated individual must take prescribed precautions to prevent the spread of infectious material from the individual's room (see 17 CCR §2516). Modified isolation is any other type of isolation, as prescribed and ordered by the local health officer and dependent on the disease involved (see 17 CCR §2517).	Ideally, persons who meet the criteria for a case of novel influenza and who do not require hospitalization should be isolated in their homes. During the earliest stages of a pandemic, when it is feasible, the home being considered should be evaluated by an appropriate authority to ensure that minimum standards (infrastructure, accommodations, resources for patient care and support) are met.
Quarantine	The limitation of freedom of movement of persons or animals that have been exposed to a communicable disease for a period of time equal to the longest usual incubation period of the disease, in such manner as to prevent effective contact with those not so exposed (see 17 CCR §2520).	May be voluntary or mandatory; same considerations as above

Table 8A.1: Non-medical containment measures: definitions, examples and considerations*

Measure	Definition	Examples and considerations
Quarantine of close contacts	The quarantine of individuals exposed to patients with communicable diseases; the contact remains separated from others for a specific period of time (up to 10 days after potential exposure) during which s/he is assessed on a regular basis for signs and symptoms of disease.	May include family members, work or school mates, healthcare workers. May be appropriate in situations in which the risk of exposure and subsequent development of disease is high and the risk of delayed recognition of symptoms is moderate. Persons in quarantine who develop fever, respiratory, or other early influenza symptoms require immediate evaluation by a healthcare provider.
Workplace quarantine	Exposed employees are permitted to work but must observe activity restrictions while off duty. Monitoring for signs and symptoms before reporting to work and use of PPE while at work are required.	This strategy is applicable in persons for whom activity restrictions are indicated but who provide essential services; reduces risk of community spread from high-risk contacts while minimizing adverse impact of activity restrictions on provision of essential services.
Focused measures to increase social distance and decrease social interactions	Interventions applied to specific groups (as opposed to individuals or communities), designed to reduce interactions and thereby transmission risk within the group. Focused measures apply to groups or persons in specific settings, most but not necessarily all of whom are at risk of exposure. Includes quarantine of groups of exposed persons and measures that apply to the use of specific sites or buildings.	Applicable in groups or settings where transmission is believed to have occurred, where the linkages between cases are unclear at the time of evaluation, and where restrictions placed only on persons known to be exposed are considered insufficient to prevent further transmission. Applied broadly, may reduce the requirement for urgent evaluation of large numbers of persons without explicit activity restriction (quarantine).
Quarantine of groups of exposed persons	Quarantine of people who may have been exposed to the same source of illness; may be useful when there is limited transmission in an area and most cases can be traced to exposure to a known transmission setting (a specific school or workplace).	Includes persons exposed to a known case at a public gathering, on an airplane or other conveyance, at a school, workplace, apartment complex, etc.
Restricting the use of specific sites or buildings or public events	A type of focused measure that may involve restricting entrance to a building or other site or requiring fever screening before entrance.	Cancellation of public events; closure of office buildings, schools, shopping malls, closure of public transportation such as subways or bus lines.

Table 8A.1: Non-medical containment measures: definitions, examples and considerations*

Measure	Definition	Examples and considerations
Community-based measures to increase social distance	Interventions applied to an entire community or region, designed to reduce personal interactions and thereby transmission risk. Includes measures applied to whole neighborhoods, towns, or cities.	Coordinated voluntary community and business closures, community-wide quarantine.
Coordinated community and business closures	Voluntary measures that coordinate simultaneous closure of offices, schools, transportation systems and other non-essential community activities, services and businesses for a specified period of time. All non-essential service personnel and community members are urged to stay at home.	Are generally voluntary and can effectively reduce transmission without explicit activity restrictions (quarantine).
Community-wide quarantine (including cordon sanitaire)	Legally enforceable action that restricts movement into or out of the area of quarantine of a large group of people or community; designed to reduce the likelihood of transmission of influenza among person in and to persons outside the affected area. Consists of closing community borders or the erection of a real or virtual barrier around a geographic area with prohibition of travel into or out of the area.	May be applicable to all members of a group in which extensive transmission is occurring, a significant number of cases lack an epidemiologic link at the time of evaluation, and restrictions placed on persons known to be exposed are considered insufficient to prevent further spread. May be unnecessary as less restrictive measures such as coordinated community and business closures may be equally effective.
Community-wide infection control measures	Use of physical barriers and hygiene measures to limit the risk of transmission.	These include respiratory hygiene, cough etiquette, hand washing and hand hygiene, use of gloves, masks, and general hygiene and disinfection. These are covered in more depth in Appendix 4 - Infection Control

*Adapted from: U.S. Department of Health and Human Services (HHS) Pandemic Influenza Plan; U.S. Department of Health and Human Services, November 2005

Table 8A.2: Possible community containment measures based on level of novel influenza activity and risk of human transmission*

Level of Influenza Activity	Response	Rationale
WHO Pandemic Phases 1-2 No novel influenza strains of public health concern in global circulation in humans	Preparedness planning	Use recommended response actions for interpandemic influenza prevention and control.
WHO Pandemic Phases 3-4 Limited novel influenza virus transmission abroad; all local cases (e.g., in California or the United States) are either imported or have clear epidemiologic links to other cases	Consider quarantine of close contacts	Although individual containment measures may have limited impact in preventing the transmission of pandemic influenza (given the likely characteristics of a novel influenza virus), they may have great effectiveness with a less efficiently transmitted virus and may slow disease spread and buy time for vaccine development.
WHO Pandemic Phase 5 Limited novel influenza virus transmission in the area (e.g., within California or the United States), with either a small number of cases without clear epidemiologic links to other cases or with increased occurrence of influenza among their close contacts	Quarantine of close contacts	Same as above.
WHO Pandemic Phase 6 Sustained novel influenza virus transmission in California, with a large number of cases without clear epidemiologic links to other cases; control measures aimed at individuals and groups appear effective	Focused measures to increase social distance; consider community-based measures	Selective use of group quarantine (focused measures) early in a pandemic when the scope of the outbreak is focal and limited; may slow the geographic spread and buy time for vaccine development.
WHO Pandemic Phase 6 Sustained novel influenza activity in California, with a large number of cases in persons without an identifiable epidemiologic link at the time of initial evaluation; individual control measures are believed to be ineffective	Community-level measures to increase social distance; consider coordinated community and business closures, and community-wide quarantine	When disease transmission is occurring in communities around the United State, individual quarantine is much less likely to have an impact and likely would not be feasible to implement. Rather, community measures and emphasizing what individuals can do to reduce their risk of infection may be more effective disease control tools.

Table 8A.2: Possible community containment measures based on level of novel influenza activity and risk of human transmission*

Level of Influenza Activity	Response	Rationale
WHO Pandemic Phase 6 (between waves or pandemic subsiding) Decreases in the number of new cases, unlinked (or “unexpected”) cases, and generations of transmission	Consider quarantine of contacts	
WHO Postpandemic Period Transmission has been controlled or eliminated, no new cases	Active monitoring in high risk populations; continue for 2-3 incubation periods after control or elimination of transmission	

*Adapted from: HHS Pandemic Influenza Plan; U.S. Department of Health and Human Services, November 2005

Table 8A.3: Threshold determinants for use in decisions about community containment measures*

Parameter	Data element
Case and contacts	Number of cases (absolute or estimated) Rate of incident cases Number of hospitalized cases Morbidity (including disease severity) and mortality Number and percentage of cases with no identified epidemiologic link Number of cases occurring among contacts Number of contacts under surveillance and/or quarantine
Healthcare resources	Hospital/facility bed capacity Staff resources Patient/staff ratio Number of ill or absent staff members Availability of specifically trained specialists and ancillary staff members Availability of ventilators Availability of other respiratory equipment Availability of personal protective equipment and other measures Availability of therapeutic medications (influenza and non-influenza specific)
Public health resources	Investigator to case and contact ratios Number of contacts under active surveillance Number of contacts under quarantine Ability to rapidly trace contacts (number of untraced/interviewed contacts) Ability to implement and monitor quarantine (staff member to contact ratio) Ability to provide essential services (food, water, etc.)
Community cooperation, mobility, and compliance	Degree of compliance with voluntary individual isolation Degree of compliance with active surveillance and voluntary individual quarantine Degree of movement out of the community Degree of compliance with community-containment measures

*Adapted from: HHS Pandemic Influenza Plan; U.S. Department of Health and Human Services, November 2005

Appendix 9 - Pandemic Influenza Risk Communication Plan

9.1 Introduction

Pandemic influenza can dramatically impact worldwide morbidity and mortality and cause economic and social disruption. Pandemic influenza risk communication strategies are a critical component of pandemic influenza preparedness. Effective communication guides the public, the news media, healthcare providers, and other groups in responding appropriately to outbreaks, adhering to public health measures, and understanding state and local response efforts.

Risk communication during a pandemic influenza must be approached differently than in many other disasters and emergencies. Pandemic influenza is likely to be a widespread and long-term event that will strain national, state, regional, and local resources and require a plan for ensuring sustained societal functions.

9.2 Objectives

The objectives of the California Department of Health Services (CDHS) pandemic influenza risk communication plan are to:

- prepare Californians for a pandemic;
- educate the public on steps they can take to decrease the spread of illness;
- communicate the importance of personal and local preparedness;
- prepare pre-event messages and materials on an influenza pandemic to share broadly;
- share public messages with healthcare providers; and
- coordinate risk communication activities across state, regional, and local levels.

9.3 Risk Communication Concepts

Communicating with the public, partners, and providers during an influenza pandemic must follow key risk communication concepts listed below:

- provide the public with information about what is known and unknown and provide interim guidance for decision making to protect individual and family health;
- coordinate and maintain consistency of messages to avoid confusion and to build credibility and trust;
- express empathy for victims;
- empower the public to protect themselves and family members;
- provide information that is scientifically and technically correct and can be understood by all facets of the public including those who are non-English speaking;

- focus information to minimize speculation, over-interpretation of data, and overly confident assessments and projections;
- establish credibility by providing immediate and on-going information in response to an intense and sustained demand; and
- provide transparent and timely dissemination of accurate, science-based information about pandemic influenza and the progress of the response.¹

9.4 Risk Communication Assumptions and Challenges

- **Public Communication:** A pandemic will be an international event. The public will turn to multiple sources for instant information, potentially resulting in conflicting or confusing messages. To reach California's diverse populations, CDHS will:
 - use multiple communications channels, such as websites, a hotline, and mass media and increase awareness of information resources;
 - model desired behavior to help the public learn and adapt to public health guidance; and
 - produce materials in numerous languages and adapt materials for the hearing and vision impaired.
- **Public Education/Community Containment:** The primary focus of a public education campaign will be self-protective actions and community containment to slow and reduce the spread of the pandemic influenza virus. Communications must help the public understand and comply with personal hygiene protective measures, community-wide interventions such as business and school closures and other infection control measures. Information will need to be shared broadly with public and private entities that will be affected by social distancing interventions likely to result in significant economic impact.
- **Travel:** International travel can quickly spread the influenza virus globally. California is at particular risk with its many ports, international airports, and tourist destinations. Communications concerning travel precautions or restrictions should be accurate and prevent discriminatory behavior.
- **Vaccine and Antiviral Shortages:** Communications must explain the lack of sufficient vaccines and antiviral medications, explain the necessity for establishing priority groups, identify priority groups, and provide resources for information.
- **Overwhelming Medical Care Demands:** A pandemic will place demands on medical care over a sustained period. Communications should include messages that help protect and maintain healthcare infrastructures, identify appropriate use of medical services, provide information regarding alternative treatment settings, direct self monitoring and reporting of symptoms, and address coping strategies and mental health needs.

¹ HHS 2005 Pandemic Influenza Plan – Supplement 10: Public Health Communications

- **Public Opinion:** Communications should increase public awareness of pandemic influenza, promote self-protection measures, explain state and local preparedness efforts, and build public confidence in preparedness efforts and government's ability to respond.

9.5 Operational Structure

This CDHS Pandemic Influenza Risk Communication Plan is consistent with the CDHS Public Health Emergency Response Plan and Procedures and the Strategic National Stockpile (SNS) Risk Communication Plan. This plan is also consistent with the strategic approach and actions identified in the 2005 CDHS Crisis and Emergency Risk Communication (CERC) Tool Kit that CDHS distributed to local health departments (LHDs).

Communication is a critical aspect of all emergency planning and response. All programs involved in planning for and responding to pandemic influenza must give priority to ensuring timely and accurate communication. CDHS will include procedures and protocols for communication actions in each phase of pandemic influenza planning and response to facilitate sharing of information within CDHS, with LHDs and other response partners, and with the public. CDHS will facilitate risk communication actions by working with pandemic influenza planning groups within CDHS, federal partners, other state agencies, and LHDs. CDHS' communication vehicles with LHDs include conference calls, frequent sharing of information via e-mail, and posting information on the California Health Alert Network (CAHAN). CDHS will use similar mechanisms to share information with other state partners and the education and business sectors.

Activation of the CDHS-Emergency Medical Services Authority (EMSA) Joint Emergency Operations Center (JEOC) initiates the transition of operations consistent with the California Statewide Emergency Management System (SEMS) and the National Incident Management System (NIMS). The CDHS JEOC/Public Information Officer (JEOC PIO) is the Emergency Preparedness Office (EPO) risk communication lead. The JEOC PIO will collaborate closely with CDHS Office of Public Affairs (OPA), affected CDHS programs such as Division of Communicable Disease Control (DCDC) Immunization Branch (IZB) and others, to coordinate a consistent response with the Governor's Office of Emergency Services (OES), LHDs, and federal, state, and other partners (Table 9.1).

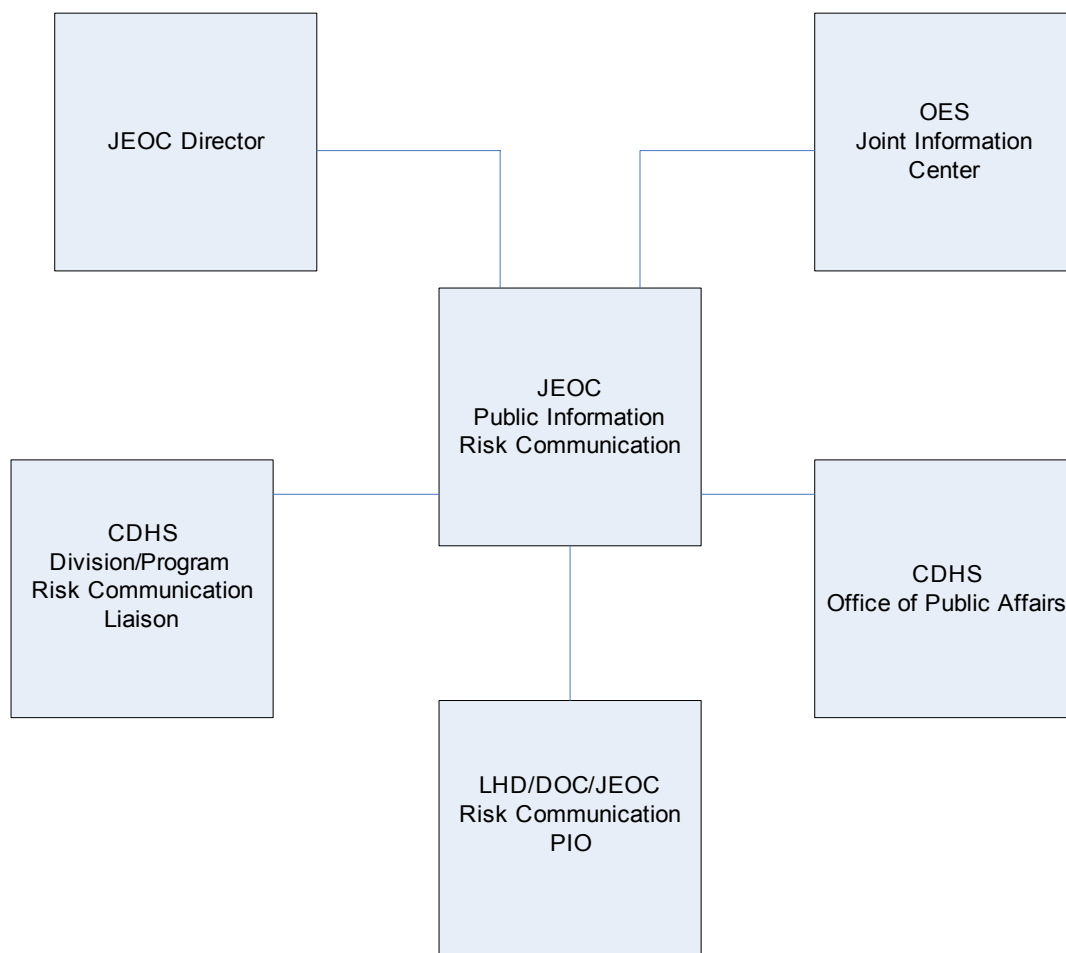
With activation of the JEOC, CDHS will assume the following roles:

- OPA: In collaboration with the JEOC PIO, OPA will maintain its lead role in providing information to CDHS Director and executive staff, CHHSA, the Governor's Office, the Legislature, and the news media.
- JEOC PIO: The JEOC PIO provides leadership on public information and risk communication and coordinates CDHS' overall response to a public health emergency coordinating the following:
 - CDHS OPA, SNS Public Information Liaison, and risk communication liaisons identified by CDHS programs engaged in the response;
 - OES Joint Information Center (JIC); and

- LHD risk communication lead/PIO.

The JEOC PIO is typically the EPO Risk Communication lead. The JEOC PIO will maintain contact and provide information to response partners to ensure consistency in public information and support of local efforts. The JEOC PIO has lead responsibility for providing public information via the EPO website, CAHAN alerts, fact sheets, sample materials/templates, and other related materials and will coordinate with EMSA through the JEOC.

- CDHS Division Public Information Liaison: DCDC or other CDHS divisions may designate a division “Public Information Liaison” (PI Liaison) to assist with public information activities and coordinate with the JEOC PIO. The PI Liaison may be located in Sacramento, Richmond, or in the field to interface with the JEOC PIO, OPA, and division staff regarding public information activities. Activities may include coordinating with content specialists, recommending public information guidance, responding to rumors in the field, arranging for the availability of spokespersons, and facilitating approval of new materials.
- OES JIC Coordination: In an emergency the OES JIC is the central point for state information on the incident. The CDHS risk communication team will continue to provide information and request involvement from the OES PIO on public information planning related to pandemic influenza through regular meetings and briefings to include other key partners. During activation, the JEOC will establish ongoing communication with the JIC and provide staffing support to its operation.
- Coordination with other state PIOs: CDHS will share information on pandemic influenza preparedness and actions for informing the public with state level partners including the Office of Homeland Security; the Departments of Mental Health, Social Services, Food and Agriculture, and Education; the Business, Transportation, and Housing Agency; EMSA and others to ensure consistency and accuracy of information to the public.

Table 9.1 JEOC Risk Communication Public Information Coordination

9.6 Risk Communications Goals, Objectives, and Strategies

9.6.1 Communication Goals

CDHS' pandemic influenza communication goals are to:

- help the public and communities to prepare for, cope with, and respond to an influenza pandemic to reduce the spread of influenza, minimize the impact on healthcare systems and social services, and prevent morbidity and mortality;
- promote self-protective behaviors and garner support for public health actions such as isolation and quarantine;
- instill public confidence in CDHS planning and response by demonstrating that CDHS and LHDs are working together with public and private agencies; and
- address rumors, inaccuracies, and misperceptions as quickly as possible and prevent stigmatization of affected groups.

9.6.2 Communications Objectives

CDHS' pandemic influenza communication objectives are to:

- develop and implement a comprehensive multi-language/multi-ethnic public information campaign that incorporates mass media, public education, a website, and an information hotline;
- through coordinated and collaborative channels (e.g., response partners, partners, stakeholders, other agencies), provide target audiences with information that is:
 - accurate and complete;
 - timely;
 - consistent;
 - comprehensive;
 - linguistically and culturally competent;
 - understandable;
- build trust and confidence by sharing what is known and not known, and providing regular updates of response efforts;
- educate and empower the public on actions they can take to prepare for pandemic influenza and other public health emergencies, self-protective measures they can take to minimize exposure, and the availability of resources; and

- coordinate release of information with LHDs and other agencies to avoid contradictions and confusion that can undermine public trust or impede containment efforts.

9.6.3 Communications Strategies

During the pre-event interpandemic and pandemic alert periods, communication strategies will focus on individual self-protective behaviors and understanding community containment actions, their purpose, and implementation.

During the pandemic period, communication strategies will focus on continuation of self-protective measures, social distancing, enforcement of community containment measures (school and work closures, etc), and communication with partners/stakeholders. The JEOC PIO coordinates actions with response agencies.

The recovery/postpandemic period will address recovery efforts, including psychosocial needs, and community return to normality. CDHS will prepare to respond to additional waves of pandemic influenza and smaller outbreaks.

9.6.4 Key Messages

Key messages should respond to issues relevant to the pandemic phase, such as:

- what California is doing to prepare;
- what California is doing in response to events outside of the state; and
- what California is doing in response to events within the state.

9.7 Target Audiences, Communications Partners and Stakeholders

For a listing of target audiences, communications partners and stakeholder, see Attachment 9A.1, 9A.2, and 9A.3.

9.8 CDHS Crisis Communications Team

Public communications during an influenza pandemic will require multi-agency coordination and collaboration within the SEMS/NIMS structure.² The CDHS crisis communications team (Attachment 9A.4) will execute the emergency response public information activities outlined in this plan. Job action sheets for the team are described in the CDHS Public Health Emergency Response and Procedures Plan.

² California Government Code requires emergency and disaster response to be coordinated via the "Standardized Emergency Management System" -- SEMS -- a cross-agency management structure that facilitates and ensures a coordinated emergency response capable of involving multiple agencies in multiple jurisdictions in California. State agencies must plan, train, exercise, and respond using SEMS. See *California Department of Health Services Public Health Emergency Response and Procedures Plan*, Appendix A.

9.9 CDHS Pandemic Response Action Steps

9.9.1 WHO Phase 1 and Phase 2 - Interpandemic Period: No novel influenza subtypes have been detected in humans, but a novel subtype that has caused human infection may be present or circulating in animals; and WHO Phase 3 and Phase 4 - Pandemic Alert Period: Human infection with no or very limited human-to-human transmission

CDHS will:

- establish and maintain regular communications through conference calls, e-mail list serve updates, and CAHAN alerts with LHDs and other partners to coordinate consistency and accuracy of messages;
- develop a comprehensive multi-ethnic, multi-language public information campaign, working with partners and stakeholders (see Attachment 9A);
- develop materials for educating the public and partners using U.S. Department of Health and Human Services (HHS) and Centers for Disease Control and Prevention (CDC) materials, California-specific information, and other materials as needed;
- display and model desired behaviors through novellas, written stories, radio spots, and other strategies;
- develop television and radio public service announcements (PSAs), and materials for other public venues (billboards, posters, bus-boards, etc.), to educate the public on self-protective actions and the value of community containment efforts;
- develop and translate into multiple languages communication resources and materials, including easy-to-read versions, such as:
 - static “cling-ons,” posters, and fliers on self-protective measures using graphics and easy to understand instructions;
 - informational materials on coordinated community and business closures;
 - tool kit with preparedness instructions for businesses (in collaboration with HHS/CDC and partners);
 - tool kit with preparedness instructions for schools (in collaboration with HHS/CDC and the California Department of Education);
 - response action sheets specific to pandemic influenza for inclusion in the LHD CERC Tool Kit.
- develop presentations that can be used to educate selected audiences on pandemic influenza preparedness;
- develop and distribute briefing packets for policy makers and share packet template with LHDs;

- post web site information for the public, healthcare providers, response partners, and the media;
- adapt materials and information developed by CDC, WHO, and others, including culturally sensitive materials in multiple languages, for dissemination via media materials, hotline, website, list-serves, LHDs, and others;
- design materials for population subgroups likely to be disproportionately affected by the pandemic;
- develop infrastructure and surge capacity for the CDHS Emergency Information Hotline to offer recorded messages and live operator capacity to provide general information and referrals for advice nurse guidance;
- provide communications training to state and LHD staff;
- determine CDHS' communications response to the first Californian diagnosed with the pandemic strain of influenza;
- reinforce training on emergency response roles and procedures for communication staff, including training on SEMS/NIMS; and
- promote public awareness of the priority groups for influenza vaccination and the rationale for selecting those groups.

9.9.2 WHO Phase 5 - Substantial Pandemic Risk: Larger clusters but still limited human-to-human transmission; sustained community transmission is possible and Phase 6 - Pandemic Period: Increased and sustained transmission in the general population

CDHS will fully activate risk communication efforts and community containment focused on slowing and reducing the spread of pandemic influenza in California. The JEOC will become the coordination center for information related to California's public health response to the influenza pandemic. The JEOC PIO, in collaboration with OPA, CDHS division risk communication liaisons, OES JIC, and LHDs, will coordinate public information during emergency activation. The JEOC-based program liaisons will review communications content for accuracy. Consistent with overall emergency activation procedures, CDHS will establish a streamlined approval process that is facilitated out of the JEOC and is approved by OPA, the JEOC Director, and the CDHS Director/State Public Health Officer.

CDHS will:

- inform the CDHS risk communication team, response partners, and LHD risk communication/PIO leads of JEOC activation and pandemic influenza risk communication actions, including the public information campaign;
- collaborate with OPA on the issuing media notification and share notices with partners;

- communicate regularly with HHS and CDC and others on developing new materials, strategies, and communication priorities;
- schedule regular briefings with partners including LHD risk communication/ PIO leads; the JEOPC PIO will participate in management briefings;
- provide CDHS spokespersons with updated key messages and troubleshooting;
- activate all components of the Risk Communication Plan in collaboration with LHDs;
- promote self-protective infection-control measures such as respiratory hygiene and hand-washing procedures;
- provide public messages that promote positive coping skills and behaviors to reduce stress;
- provide public awareness of coordinated community and business closures and “stay at home” messages;
- reinforce social distancing messages such as avoiding crowded areas and events to minimize exposure;
- model desired behavior with mass media messages and provide information and support for community containment strategies and self-protection and monitoring actions;
- post information on CAHAN and the CDHS website with links to other credible sources;
- ensure the full-operation of the Influenza Information Hotline to provide recorded messages on self-protection and community containment and live operator assistance regarding when to stay home or seek medical care;
- help LHDs promote designated influenza medical facilities;
- schedule regular briefings with the press and share all press releases with response partners via e-mail and CAHAN;
- activate the SNS risk communication plan when vaccine becomes available and/or prophylaxis is provided to the general public; and
- use CDHS PIO surge capacity staffing for continued operation and continue to support public information efforts of LHDs.

9.9.3 Recovery/Postpandemic Period

CDHS will:

- continue all pandemic phase actions as needed to address additional outbreaks of influenza and additional waves of disease;

- continue collaboration with mental health partners to incorporate recovery-focused messages into public information; and
- support community recovery efforts by repeating and promoting self-protective messages as community norms.

Attachment 9A - Risk Communications Resources, Tools, and Materials**9A.1 Risk Communications Target Audiences**

CDHS will target the following audiences for risk communication messages and information:

- general public;
- media, including ethnic media;
- local health departments (LHDs);
- legislators, city, state, and county officials;
- CDHS staff;
- healthcare community (healthcare providers, hospitals, clinics, doctors, nurses, etc.);
- business and community leaders;
- ethnic communities;
- first responders;
- agricultural workers;
- tourists;
- disabled;
- homebound;
- low-literacy;
- homeless;
- schools and children; and
- seniors

9A.2 Risk Communications Partners

- Centers for Disease Control and Prevention (CDC)/U.S. Department of Health and Human Services (HHS)
- California Health and Human Services Agency (CHHSA)
- CDHS Divisions and Programs

- Governor's Office of Emergency Services (OES)
- Governor's Office of Homeland Security
- California Department of Food and Agriculture
- Emergency Medical Services Authority (EMSA)
- Other state departments and agencies including:
 - Business, Transportation, and Housing Agency;
 - Department of Aging;
 - Department of Corrections and Rehabilitation;
 - Department of Education;
 - Department of Industrial Relations;
 - Department of Mental Health;
 - Department of Social Services;
 - National Guard; and
 - Office of the Attorney General
- Legislature
- Local health and mental health departments
- County Health Executives Association of California
- California Conference of Local Health Officers
- Tribal entities
- Medical associations/societies
- Hospitals and clinics
- Emergency responders
 - fire/rescue; and
 - law enforcement
- Red Cross and other community-based organizations.

9A.3 Risk Communications Stakeholders

- City and county elected leadership and administration
- Civic organizations and unions
- Business and community leaders
- Community-based organizations
- Homeless shelters
- Assisted living facilities
- School districts and PTAs
- Ethnic organizations
- Mortuaries/funeral homes
- Children's care services
- Anti-viral manufacturers and distributors
- Vaccine manufacturers and distributors
- Large health insurance organizations
- Healthcare providers

9A.4 Communications Team

Public Information /Risk Communication Co-Leads:

- CDHS Deputy Director of OPA, and
- CDHS EPO Risk Communications Lead.

Full activation in response to a pandemic may involve the following roles, using existing CDHS staff to augment the Communications Team:

- media assistants;
- LHD coordination and support;
- content and message coordinator;
- influenza hotline analyst;

- direct public outreach coordinator;
- partner/stakeholder coordinator;
- multi-cultural/special populations outreach coordinator;
- department/division public information liaisons;
- healthcare provider outreach coordinator;
- rumor control analyst; and
- web masters.

9A.5 Risk Communications Tools, Materials, and Tasks

9A.5.1 Material Resources

- Fact sheets
- Frequently asked questions (FAQs)
- Talking points
- Questions and answers (Q & As)
- Sample press releases for first case and first death, coordinated community and business closures, protective measures, etc.
- Posters, “cling-ons,” signs, stickers, etc., for distribution to LHDs, hospitals, clinics, restaurants, transportation portals (airports, train stations, ports, bus stations), gas stations, retail outlets, and other public gathering places
- Websites (CDHS, OES, partner/stakeholder sites, central site, search engine pick-up, bulletin boards, list-serves, links)
- Hotline (activation procedures, script, surge control, translation, staffing)
- Newsletters
- Materials in multiple languages and low literacy text
- Material testing
- Key messages
- Radio scripts, billboards, bus boards, poster text and radio public service announcements

9A.5.2 Media Outreach

- Guidelines and instructions for media relations
- Press conferences
- Press releases
- Daily briefings
- Media web postings
- Video and audio clips
- Video conferencing
- Radio actualities
- Radio and TV Public Service Announcements (PSAs)
- Electronic press kits
- Message monitoring

9A.5.3 Media Management

- Media contact lists
- Ethnic media outreach
- Media monitoring
- Media contact logs

9A.5.4 Public Education

- Web site (educational materials, web site promotion) including materials for key audiences such as providers
- Toll-free phone lines
- Presentations targeted toward community-based organizations for education
- Message dissemination
- Educational opportunities such as town halls, community presentations, etc.
- Translation services

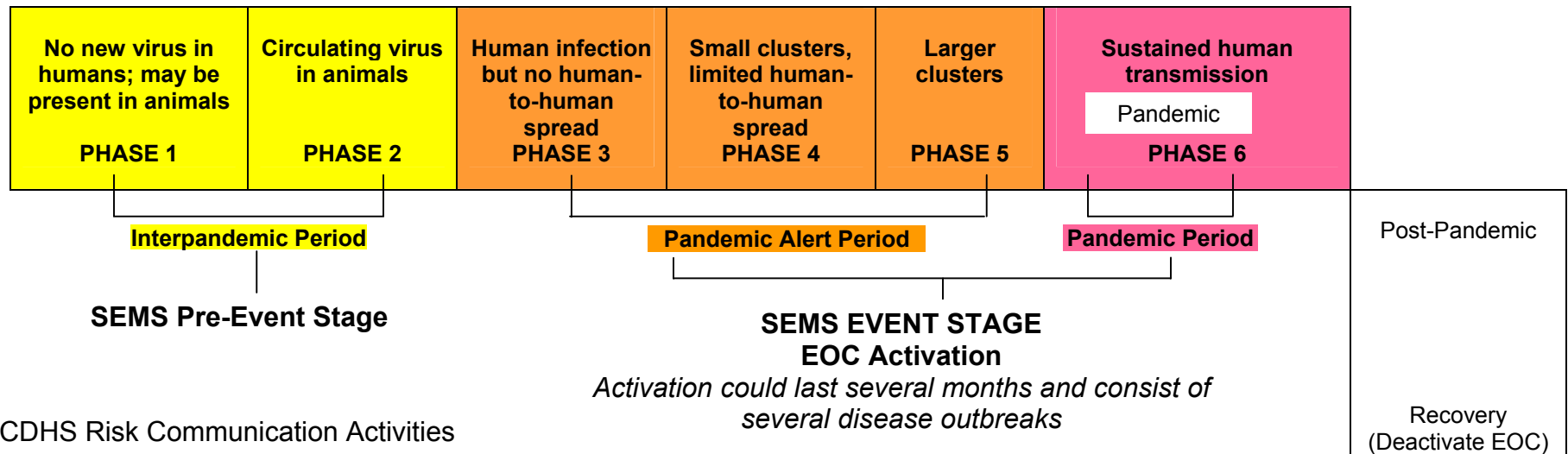
- Partner outreach and briefings
- Outreach to stakeholders and special populations

9A.5.5 Team Management

- Examine current issues and messages daily
- Evaluate effectiveness of strategies and messages, update/revise as needed
- Discuss feedback from information loops
- Determine message of the day and disseminate to team
- Train spokespersons and update as needed (subject matter experts, bi-lingual, training)
- Build communication staff surge capacity (recruitment and training)
- Ensure key staff is knowledgeable about NIMS/SEMS and emergency response process
- Update team on status of planning and response
- Participate in tabletop drills, exercises, and briefings

PANDEMIC INFLUENZA RISK COMMUNICATION PLANNING AND RESPONSE

WHO Phases



CDHS Risk Communication Activities

<ul style="list-style-type: none"> Develop CDHS Pandemic Influenza Communications Plan with Risk Communication annex 	<ul style="list-style-type: none"> Develop key message points and distribute to LHDs Develop templates for 1st case in California, 1st death, vaccination of priority groups, limited or no availability of vaccine and antiviral medications, etc. Develop crisis web site Secure hotline messages and surge capacity Develop and maintain relationships with potential communication partners for community outreach. 	<ul style="list-style-type: none"> Provide focused spokesperson training Develop briefing packet for policy makers and distribute Develop Q & A regarding isolation and quarantine Train CDHS staff for PIO surge capacity Hold tabletop exercises with partners Continue briefings with OES, Homeland Security, and LHDs Initiate communications with partners. 	<ul style="list-style-type: none"> Activate pre-developed materials/web site/hotline Operate all EOC Risk Communication Actions Ongoing communication/support with OES, JIC, OPA, DCDC, Labs, LHDs, CDC Monitor media, counter rumor control Press releases, press conferences, fact sheets Activation of SNS Risk Communication plan as indicated. 	<ul style="list-style-type: none"> Continue working with DMH and partners regarding recovery-focused messages. Maintain regular communications with partners.
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9A.6 Web Sites/Fact Sheets

The links listed below were active as of October 2005. However, web sites can change without notice.

Government

www.pandemicflu.gov

Pandemic Influenza Fact Sheet

<http://www.cdc.gov/flu/avian/gen-info/pandemics.htm>

Avian Influenza Fact Sheet

<http://www.cdc.gov/flu/avian/gen-info/facts.htm>

Guidance to Travelers

http://www.cdc.gov/travel/other/avian_flu_ah5n1_031605.htm

Interim Guidance for U.S. Citizens Living Abroad

http://www.cdc.gov/travel/other/avian_flu_ig_americans_abroad_032405.htm

Sample CDC News Conference Transcript

<http://www.cdc.gov/od/oc/media/transcripts/t040127.htm>

Managing Anxiety in Times of Crisis

<http://mentalhealth.samhsa.gov/cmhs/managinganxiety/default.asp>

California Department of Health Services

www.dhs.ca.gov

9A.7 Influenza Background Information

- **CDC:** Presents information on the symptoms, treatment, and complications of the disease, prevention and control, the types of influenza viruses, questions and answers on symptoms, vaccination, and myths. <http://www.cdc.gov/flu/avian/>.
- **National Vaccine Program Office:** Presents a historical overview of pandemics that occurred throughout the past century (Spanish Flu, Asian Flu, Hong Kong Flu), and three influenza scares (Swine Flu, Russian Flu, and Avian Flu). www.dhhs.gov/nvpo/pandemics
- **World Health Organization:** Defines an influenza pandemic, explains how a new influenza virus can cause a pandemic, presents the consequences of an influenza pandemic, explains the global surveillance systems, and provides links to other pandemic plans from other nations. www.who.int/csr/disease/influenza/pandemic/en

9A.8 Additional Response Resources

- **The Public Health Preparedness and Response Capacity Inventory:** Resource for state and local health departments undertaking comprehensive assessments of their preparedness to respond to bioterrorism, outbreaks of infectious disease, or other public health threats and emergencies.
www.dhs.ca.gov/epo/PDF/NPSsmpxv1.pdf
- **CDC Cooperative Agreements on Public Health Preparedness:** State and local public health preparedness for and response to bioterrorism, other outbreaks of infectious diseases, and other public health threats and emergencies.
www.bt.cdc.gov/planning/continuationguidance
- **Epidemic Information Exchange:** Web-based communications network for information exchange among CDC, state and local health departments, and other public health professionals. www.cdc.gov/mmwr/epix/epix.html
- **Centers for Public Health Preparedness:** A national system for competency-based training tools for the public health workforce. www.asph.org/acphp
- **Strategic National Stockpile:** Information on the availability and rapid deployment of life-saving pharmaceuticals, antidotes, other medical supplies, and equipment necessary to counter the effects of nerve agents, biological pathogens, and chemical agents.
www.bt.cdc.gov/stockpile

9A.9 Nongovernmental Organizations

- Association of State and Territorial Health Officials (ASTHO) – www.astho.org
- Infectious Disease Society of America – www.idsociety.org
- National Foundation for Infectious Diseases – www.nfid.org
- Institute of Medicine (IOM) – www.iom.edu
- World Health Organization (WHO) – www.who.org

9A.10 Influenza Pandemic Enhancements to CDHS Crisis Website Template

Blue text needs to be replaced with appropriate information.

Red text (instructions) should be deleted.

Black text is what will appear on final Web site.

[This enhancement is adapted from the Crisis Web Site Template and includes information to be added in the event of a Pandemic Influenza outbreak. New sections have been noted with asterisks.]

Information About [Nature of the crisis]

CDHS Home

[This is a link to
<http://www.dhs.ca.gov/>]

Emergency Preparedness Office (EPO) Home Page

[This is a link to
<http://www.dhs.ca.gov/EPO/>]

Información Sobre [la Emergencia]

[This is a link to a
separate menu of items
in Spanish]

**[Below this, list
additional translation
languages as
appropriate]**

This section should contain emergency information, referral numbers, and a restatement of the emergency message points.

Message from the Director

**[NAME AND TITLE]
[ORGANIZATION]**

Our thoughts are with the victims of the [insert crisis event] and their family members. We know this is a difficult time for all Californians. There is still a lot we do not know about [insert crisis event], but as we confirm the details, we will make them public. [The following sentence should be posted immediately and then updated after 24 hours:] Our understanding at this time is that approximately [number of victims] are known to have been exposed to [insert agent].

The California Department of Health Services is working with the [name of confirming agency] and the [name of affected county] Health Department to assess the situation, protect the general public and monitor the impact of the [insert crisis event.] As a precaution, we are recommending that residents of [name of affected area] [take common-sense steps to stop the spread of germs. Wash hands frequently with soap and water, cover coughs and sneezes with tissues, and stay away from others as much as possible if you are sick.]

State and local officials are working with federal authorities to ensure that all who have been affected by the [insert crisis event] are receiving appropriate treatment.

We will continue to provide you with updates as new information becomes available.

This information last updated on [date] at [time]

Facts About the Current Situation [Link to page with information on what happened and current danger]

Additional information about the current crisis.

Map of the Affected Area [Link to an appropriate map, including an outline of any evacuation/shelter in place/quarantine boundaries. This will have to be supplied to EPO by the appropriate department.]

A detailed map of the area affected by the current crisis.

Information for Local Residents [Link to page on where to go for treatment, medicine adherence and other local information]

Information for residents of [affected area].

Resources [Link to resources page, which should include the following items: California-specific fact sheets, links to specific documents generated by pre-approved partners, etc.]

Additional information including web links to other sites.

Links to Emergency Services [Links to other pre-approved Web resources]

Links to Web sites providing emergency information and services.

News Releases [Link to all news releases issued by the department and pertaining to the emergency]

News releases and updates on the current situation.

For more information visit the HHS Pandemic Influenza site at [Link to appropriate HHS Web page]

[End of Home Page]

9A.11 Media Tracking Log

It is important to track all the media inquiries received and this tracking tool can be used for this purpose. One form should be used for each media call.

Deadline:

___ 2 hours ___ Today a.m. ___ Today p.m. ___ ASAP ___ Other

Media Outlet:

↑ Local ↑ Regional ↑ National

___ TV ___ Daily/Wire ___ Radio ___ Magazine ___ Other

Caller's Name: _____

Organization: _____

Caller's contact information: Phone(s): _____

Fax: _____

E-mail: _____

Action(s):

↑ Return call expected from press officer

↑ Return call with E-mail or fax

↑ Other _____

Action Completed:

↑ Date and time _____

↑ Date and time _____

↑ Date and time _____

No action needed; call closed by:

↑ Question answered

↑ Referred to Internet

↑ Referred to subject matter experts

↑ Other _____

Comments:

Taken by: _____

Time: a.m. _____ p.m. _____

Date: _____